Royal Society of Biology (RSB) – Written evidence (LSI0101)

The Royal Society of Biology (RSB) is a single unified voice, representing a diverse membership of individuals, learned societies and other organisations. We are committed to ensuring that we provide Government and other policymakers, including funders of biological education and research, with a distinct point of access to authoritative, independent, and evidence-based opinion, representative of the widest range of bioscience disciplines.

<u>Summary</u>

1. Life Sciences are a broad and vital component of the research and innovation landscape and deliver key societal and economic benefits. The biosciences collectively contribute to growth and enhanced wellbeing and there is scope for greater combined benefits from across areas sharing skills, subject and business knowledge, and strategic focus. Strategic support in terms of regulation, funding and infrastructure could increase growth and avoided costs among other outcomes.

2. Life science research is a high skilled and highly international activity with global collaborations and dynamic movement of people in research and allied roles. The right regulatory, funding and social environment to support collaborative and international activity is vital. International researchers must be able to work in the UK, and UK researchers must be able to work abroad in order to maximise skill use and return on human and fiscal investment.

3. Brexit poses significant challenges to the UK life science research and development ecosystem which has benefited significantly, and increasingly in recent years, from EU access, funding and infrastructures. Near term certainty about the capacity to remain part of collaborative networks and within competitive funding mechanisms is increasingly needed. In the current atmosphere of uncertainty many researchers are making career-move decisions away from the UK. This may threaten research capacity.

4. There is a pressing need to enhance the funding environment in the UK and to accelerate towards the Government target of 3% of GDP by 2023 ahead of time. Potential loss of EU funding access could seriously undermine current strengths.

5. Regulation of science and products will need to reflect international trade and collaboration pragmatically. It is important that the future regulatory environment of the UK builds holistically on knowledge about human and ecosystem health and provides protection.

<u>Detailed response:</u>

1) How can investors be encouraged to invest in turning basic life science research into new innovations in treatment? Why has investment been lacking in this sector? Does the research base have the necessary infrastructure to be world-leading?

1.1 Definitions and scope

The Royal Society of Biology uses the term 'life sciences' to describe all areas of the science of life, from molecules through whole organisms to ecosystems, and across all biological specialisms.[1] Under this definition, the life sciences extend far beyond healthcare, pharmaceuticals and treatment. The Committee may wish to consider the potential confusion beyond policy circles about the use of the term 'life sciences' in relation to a sector-specific Industrial Strategy with a predominant focus on biomedicine and healthcare. Developing a broad strategy – or linked strategies for major sectors – should beneficially include areas of innovation such as synthetic and microbial biology, industrial biotechnology, agri-food and forestry, among others. **Considering the full range of bioscience in the strategy will be necessary to achieve inclusive growth and benefits for people in terms of dealing with the interface between food and health, the implications of climate change, sustainable land management and many other areas.**

1.2 Our response to this inquiry is informed by experience of working in many areas of bioscience where innovation, translation and commercialisation of research are pertinent issues. We wish to emphasise the vital importance of supporting fundamental, 'blue skies' research, as well as developing research that addresses defined problems and applications. Fundamental research increases understanding of ourselves and the world around us, and is often the source of breakthroughs that lead to new products in ways that cannot be predicted or commissioned. Applied and translational research are also essential, and the effects are still being felt of the near-market cuts to research in agriculture and horticulture of the 1980s, with a reduced pipeline of good applied science available to industry in some fields. **It is important that the portfolio of publicly-funded research achieves a balance of fundamental, translational and applied programmes.**

1.3 Barriers to investment

Several barriers may deter the investment needed to develop new innovations into treatments and other products. Lack of investment is often ascribed to the high risk involved. In drug development, concentrating resources on a single lead candidate increases the risk of complete failure and the loss of investors' money, but the alternative situation in which resources are spread thinly over multiple projects also risks providing insufficient funding and momentum for individual products to reach the market. Many investors favour investments with shorter terms for returns than those available in this sector. Investor mind-sets are changing, however, and there are now more investors prepared to take a much longer time horizon for new investments. Patient capital (long-term capital) and a good view of bioscience opportunities and requirements are needed.[2]

[1] Royal Society of Biology. https://www.rsb.org.uk/index.php/about-us

[2] HM Treasury. Financing growth in innovative firms: consultation https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/634338/financing_growth_i

1.4 Investment may also be limited by low awareness of the opportunities available. Those working in the sector could help to 'sell' the opportunities to a wider audience, to promote understanding and interest. However, academic researchers are rarely trained to engage with investors, and unless they wish to undertake such training and are able to do so, need the help of others to enable the commercialisation of research.

1.5 Innovator companies have limited time within which to market their products and recoup investment before the appearance of generic products. This may reduce the incentive to bring certain types of medical and veterinary treatments to market. However, the market rules of many trading areas are relevant here and will influence decisions depending upon the intended market.

1.6 Encouraging investment
Encouraging the development of effective collaborations between researchers and industry can be achieved by supporting the growth of research hubs and networks, enlarging the Catapult and Catalyst schemes, and developing larger public-private partnerships.

1.7 With the right encouragement, scientific leaders can be good at joining up distinct and non-obvious frontiers of discovery across disciplines and sectors, from which many promising scientific innovations can come. Research Councils and other overarching bodies could stimulate this activity by creating forums that facilitate discussions between disciplines, protecting and presenting opportunities for funding and development with other parties.

1.8 Research institutes can bring together academia and industry. The development of larger hubs with a concentration of small biotechnology firms and venture capital companies has been successful in the US, having developed in Boston and San Francisco, for instance. While there are clusters of biotechnology firms in Oxford, Cambridge and London, these are not yet sufficiently integrated to act as a single hub, and further efforts to unify these into a southeast centre would make it easier for venture capital to identify promising ideas and companies. Further Bioscience clusters continue to develop across the UK, including the BioVale cluster in Yorkshire and the Humber, an IB hub in Scotland around IBioIC, and a biorefining cluster in Wales supported by the BEACON project. Additional, strategically placed clusters should also be supported and developed elsewhere (whilst maintaining the integrity of current hubs), for example in the Midlands.

1.9 Maintaining adequate support to research institutes run directly by the individual research councils and those sponsored by Government departments, such as executive non-departmental public bodies Royal Botanic Gardens Kew and the Natural History Museum, and executive agencies such as Forest Research, will be important to maintain

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n_innovative_firms_consultation_web.pdf

contributions to public-domain research. Outputs from these establishments are of use in supporting regulation and policy both broadly and in niche areas in a cost effective manner. Such research outputs are generally near-market and highly valued by industry due to the ease of translation into innovative products and services.

1.10 The Catalyst schemes[3,4] between BBSRC and Innovate UK were very successful in fostering interactions between academics and industry. For instance, the Catalyst schemes encouraged GSK to develop collaborations with the Universities of Strathclyde[5] and Birmingham[6] to support the translation of basic knowledge into new or improved industrial processes. The BBSRC Networks in Industrial Biotechnology and Bioenergy (NIBB) have also been successful in encouraging collaborations between academia and industry, and have generated a strong sense of community. [7] Funding for the Catalyst and NIBB schemes has not continued, leaving previously funded Feasibility Projects without follow-on funding opportunities, which are especially important to establish Proof of Concept since other schemes will support only more developed and validated technologies (including many EU-funded schemes to which the UK may not have access in future). An extension of the NIBB funding and a replacement for Industrial Biotechnology Catalyst funding are important to maintain the current momentum, as such schemes can take some time to begin to work efficiently. The recently-announced closure of the Precision Medicine Catapult is a regrettable loss of a dedicated centre for supporting this critical area of medicine.[8] Towards the far end of development, the loss of the European Medicines Agency from Britain risks a wider loss of jobs, expertise, investment and development incentive in the UK.

1.11 The recommendations within the O'Neill Report on Antimicrobial Resistance provide a key example of the incentives and stimuli needed to boost R&D in an area which has been historically overlooked and underrepresented.[9] Work- such as that championed by the DriveAB[10] project- towards translation of the proposals made within the report into viable mechanisms for responsible use of antibiotics, should not be neglected. The approach in this report may be applied to other areas of the UK science industry, that require support and external investment, providing an opportunity for the UK to be a global leader in various

[3] Agri-Tech Catalyst http://www.bbsrc.ac.uk/funding/filter/agri-tech-catalyst/
[4] Industrial Biotechnology (IB) Catalyst http://www.bbsrc.ac.uk/innovation/collaboration/innovate-uk-competitions/industrial-biotechnology-catalyst/
[5] Enhancing the yield of industrial Actinomycete fermentations http://gtr.rcuk.ac.uk/projects?ref=BB%2FN023544%2F1
[6] Developing a Quorum Sensing system into an efficient and economical way to control industrial production of high value products http://gtr.rcuk.ac.uk/projects?ref=102300
[7] Networks in Industrial Biotechnology and Bioenergy (BBSRC NIBB) http://www.bbsrc.ac.uk/research/programmes-networks/research-networks/nibb/
[8] Precision Medicine Catapult to close http://www.researchresearch.com/news/article/?articleId=1368789
[9] Tackling drug-resistant infections globally: final report and recommendations. The review on antimicrobial resistance, chaired by Jim O'Neill. https://amr-review.org/sites/default/files/160525_Final%20paper_with%20cover.pdf
[10] DriveAB http://drive-ab.eu/about/

areas, with a positive impact across the world. Similarly, the recent Chief Medical Officer's Annual Report discusses ways to support the application of new discoveries (in this case, in genomics) in the health sector.[11] This includes calls to set national standards, centralised laboratory services and investment in training and research. **Such ventures will require collaboration and investment from both the public and private sectors. Importantly, these initiatives need critical judgement to ensure that capacity is not lost in any vital area, which could jeopardise current delivery and future potential.**

1.12 Infrastructure

In several particular specialties of the life sciences, UK infrastructure (in terms of access to the appropriate processes, resources and equipment) is world renowned. Examples include UK Biobank,[12] Alspac,[13] Whitehall II,[14] ELIXIR,[15] Diamond Light Source,[16] The European Bioinformatics Institute (EMBL-EBI),[17] The UK Stem Cell Bank,[18] the CLIMB project,[19] and cohorts at the Centre for Longitudinal Studies.[20] The research base needs access to infrastructure at all scales, from labs to regional, national and international facilities. To be world-leading, UK researchers need continued access to international infrastructure, including facilities located within EU member states, such as Euro-Bioimaging.[21] **A particular concern upon the UK's departure from the EU is the future of the EU Reference Laboratories – an important network that function as a source of expertise and scientific advice on areas such as food safety and plant, human & animal health.[22] Access to reference laboratories based in other EU Member States may be lost, representing a loss of infrastructure, mitigation of which will be crucial post-Brexit.**

1.13 The UK's research base often has better infrastructure and facilities in its research institutes than in universities where most training takes place. The next generation of researchers are therefore not always being trained on 'state of the art' instrumentation and facilities.

1.14 A particular problem in the UK can be the system of charging to access infrastructure, with full economic cost (FEC) recovery, amortization and accounting creating a significant administrative burden. This is not

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[11] Generation Genome: Annual report of the Chief Medical Officer 2016 https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/631043/CMO_annual_report_generation_genome.pdf

[12] UK Biobank. http://www.ukbiobank.ac.uk/

[13] Avon Longitudinal Study of Parents and Children. http://www.bristol.ac.uk/alspac/

[14] Whitehall II (also known as the Stress and Health Study) http://www.ucl.ac.uk/whitehallII

[15] ELIXIR https://www.elixir-europe.org/

[16] Diamond Light Source http://www.diamond.ac.uk/Home.html

[17] European Bioinformatics Institute (EMBL-EBI) http://www.ebi.ac.uk/

[18] The UK Stem Cell Bank http://www.nibsc.org/ukstemcellbank

[19] Cloud Infrastructure for Microbial Bioinformatics www.climb.ac.uk

[20] Centre for Longitudinal Studies. http://www.cls.ioe.ac.uk/

[21] Euro-Bioimaging provides access to cutting-edge biological and medical imaging technologies, technical support and advanced training to researchers in Europe. http://www.eurobioimaging.eu/

[22] European Union Reference Laboratories. https://ec.europa.eu/jrc/en/eurls

replicated in all countries which offer access to infrastructure that is free at the point of access for researchers across institutes, and technical support is commonplace. An example is access to cryo-electron microscopes (cryo-EM) for structural studies of drug targets, which is so prohibitively expensive in the UK that access is impossible for all but the most highly funded.

1.15 Ongoing use and development of infrastructure requires support for staff scientists and technicians as well as hardware, to provide training and expertise. A greater provision of technical support would also allow early career researchers to use their time more effectively.

1.16 There are opportunities to improve sharing of infrastructure to make the most of our resources. There are some efforts to share equipment, for instance between academic researchers and pharmaceutical companies,[23] among consortia such as the N8 and White Rose partnerships,[24,25] and via the 'equipment.data', 'Kit-Catalogue' and 'frictionless supercomputing' projects developed by Jisc through partnerships with the Universities of Loughborough and Southampton and the Engineering and Physical Sciences Research Council. [26] **The opportunity to share infrastructure is yet to be fully exploited. Doing so will require more structured networks between universities and research institutes, and associated, searchable databases, but will ultimately speed up work and save on infrastructure costs.**

1.17 **It has also been highlighted that – in order to maximise the use of data within the bioscience sector and across and between other sectors- work is needed to create effective and efficient frameworks for data sharing, and access to the benefits derived from the use of data, in a legal and ethical context.** Such frameworks should tackle issues which are currently hindering productivity in the use of data, such as the now frequent need to merge data from different sources in research (for example within and between the veterinary and public health sectors), requiring cooperation within and between establishments, organisations, bodies and networks.

1.18 Efficient resource sharing is discouraged by the current VAT implications. VAT is zero-rated for certain equipment used in medical or veterinary research. Extending this to apply to other research with direct impacts on health, wellbeing and societal benefit could be considered. Appropriate equipment sharing within the HEFCE research excellence framework might also provide an incentive.[27] The development of

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[23] MRC forges two new deals with industry to speed drug discovery https://www.mrc.ac.uk/news/browse/mrc-forges-two-new-deals-with-industry-to-speed-drug-discovery/

[24] N8 Research Partnership http://www.n8research.org.uk/

[25] White Rose university consortium https://www.whiterose.ac.uk/

[26] Equipment sharing made easy. https://www.jisc.ac.uk/rd/projects/equipment-sharing-made-easy

[27] A response from the Society of Biology to the Department for Business, Innovation and Skills on proposals for long term Capital Investment in Science and Research; July 2014; https://www.rsb.org.uk/images/SB/Proposals_for_long_term_Capital_Investment_in_Science_and_Research-Society_of_Biology.pdf

standard agreements for research collaborations (for instance the Lambert toolkit[28]), could play a role in overcoming some of these challenges.

2) Why has the UK underperformed in turning basic research in the life sciences into intellectual property? What needs to be done to address this historic weakness in the UK and grow new companies to commercialise new research and related technologies in the life sciences?

2.1 Challenges in protecting IP
Technology transfer offices within universities and institutes face complex challenges, often with small budgets, and lacking capacity to achieve objectives; enhanced resources could improve this. Academic scientists may present inventions at short notice prior to publication, leading to suboptimal patent filings. Difficulties commonly arise 12 months after the priority filing, when the patent reaches the Patent Cooperation Treaty (PCT) stage: funding is often lacking for researchers to conduct exemplification work prior to the PCT filing. This can result in weak patents that do not cover the broadest possible claims, squandering potential commercial value. Alternatively, universities may feel there has been insufficient progress on the project to justify the cost of continuing to protect the IP. This leaves the IP unprotected, the money spent to this point is wasted, and scientists are left discouraged from repeating the process with subsequent IP. To encourage work to exemplify patents in the 12 months after filing, specific translational funding could be considered. Government could also contribute to developing regional capacity for evaluation and advice on IP potential from academic research innovation in the life sciences. Better availability of patent funding could also reduce the financial barrier to protecting IP.

2.2 When spin-outs happen, some of our members report that university technology transfer offices can expect to retain a high equity stake in the new companies; almost inevitably, these companies will require further investment, diluting the value of the initial share-holding, or the company will not survive.

2.3 The type of data required to show efficacy of a new drug candidate is expensive, both financially and in terms of the expertise required. In the life sciences, the costs involved in the pursuit of large IP portfolios, or patent claims which hold adequate weight, currently favours larger companies and disproportionately challenges start-ups. Similar issues are encountered by medical start-ups seeking the regulatory approval to enter clinical trials with a drug candidate. This model follows the example of the technology industry and may not be appropriate for the life sciences sector.

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[28] The Lambert Toolkit; URL: https://www.gov.uk/guidance/university-and-business-collaboration-agreements-lambert-toolkit

2.4 Supporting innovation in research culture
Educating scientists about IP protection would help to increase awareness of the process. Understanding that the initial patent is only the start of the process, with more data needed for PCT, and subsequent filings to protect specific aspects of the IP, is important. Understanding that further work may be needed at relatively short notice, should patent examiners present a challenge to the validity of the patent application, is also key. Training on patent writing and patentability could be offered to researchers and institutions.

2.5 Training could also encourage a more innovative mind-set, early. We hear comments that, in contrast to those in some other countries, UK schools, colleges and universities tend to train students to be employees, but do not provide skills in entrepreneurship, business development or awareness of the applications of science to encourage students to become employers or innovators. It is suggested that in consequence fewer are willing to take on the risk of launching their own businesses.

2.6 In academic settings, researchers may have little incentive to pursue the development of research into new products or processes. Commercialising requires significant investment in areas outside the traditional training, expertise and comfort zone of typical academic researchers, who may also lack experience in assessing risk. When this is combined with lack of professional recognition, a large workload and the long timescales required for success, commercialisation can appear relatively risky. Providing researchers with recognition for publishing patents as well as high impact papers could help to redress this. It should also be noted that some tension exists between the aims of protecting IP and of the open science culture among many academic scientists, in which ideas, methods and data are published in publicly available papers. Academic researchers are also under pressure to publish work quickly to satisfy requirements for the Research Excellence Framework (REF), which reduces the incentive to begin the lengthy IP process. Improving the provision of technical support could also help by reducing constraints on the time of academic staff.

2.7 Bringing a new product to market requires several different skill sets: creating a new start-up company requires a visionary leader; growing a small company needs all-round business skills including fundraising; and commercialising a product needs marketing expertise. These are skills that may not align with those required for academic research, and some researchers may not wish to become entrepreneurs themselves. Recognising individuals' strengths, and working with others to ensure that the necessary skills are available, can enable progress toward commercialisation.

2.8 It is important that commercialisation is not merely something that occurs at the end of the research process, but that industry or user engagement and feedback are an integral part of research throughout. Coordination and a common purpose are needed through the whole system, with funders, scientists and knowledge exchange activities all connected with industry or user communities, so that research addresses the genuine needs. This coordination needs to include all stakeholders, including those in public health, agriculture, etc, who have a valuable perspective in this and have often bridged the gap between fundamental and translatable science.

2.9 Attitudes to translational research may be similar, in that researchers may be deterred from pursuing outcomes in this field due to concerns over project length, expense, difficulty and risk. Translational research is also highly dependent on cross institutional collaboration, in order to pool cross-disciplinary expertise. The seeding drug discovery scheme[29] from the Wellcome Trust is one example of support provided to translational research, support to similar existing schemes, and new ones, would be welcomed by the biosciences sector.

2.10 Research grant proposals often state the potential benefits of the work they propose towards addressing national or international needs. In many cases, researchers and their institutions have no opportunity to develop ideas beyond the research itself in order to bring about these benefits, but where that opportunity exists it may be possible to encourage grant-holders to take some responsibility for stimulating the next steps. For example, in research institutes and labs, grant funding could be accompanied by some accountability for developing work beyond publication.

2.11 There is concern that the creation of UKRI as a single body driving research and innovation may lead to investment focused more narrowly within prioritised sectors of the life sciences. The potential for direct political influence on UKRI decisions is concerning. In line with the Haldane principle, research funding decisions guided and supported by UKRI should be made by researchers and experts with a research background at project level. **With careful implementation, UKRI has the potential to create a more effective innovation pipeline, reducing the problem of people working in 'silos'. Support for multi-disciplinary and inter-disciplinary research remains a key recommendation as identified in the Nurse Review, which set out the aims for UKRI,[30] and there are established cross-Research Council programmes on which to build,[31] such as the Synthetic Biology for Growth Programme.[32] By their nature some aspects of bioscience research remain focussed on fundamental discovery and exploration, and these vital elements and activities must be well integrated and supported within the overall programme.**

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[29] Wellcome Trust Seeding Drug Discovery Scheme: https://wellcome.ac.uk/what-we-do/directories/seeding-drug-discovery-projects-funded

[30] The Nurse Review – Ensuring a Successful Research Endeavour - Research Councils statement http://www.rcuk.ac.uk/media/news/151119/

[31] Cross-Research Council programmes http://www.bbsrc.ac.uk/research/programmes-networks/cross-council/

[32] Synthetic Biology for Growth Programme. http://www.bbsrc.ac.uk/research/programmes-networks/synthetic-biology-growth-programme/

2.12 Funding restrictions

A gap in funding support between that provided by the Research Councils for basic science, and that provided by (e.g.) Innovate UK for work on near-to-market innovation, is a barrier to work on validating and developing new innovations at scale or in relevant environments (i.e. at technology readiness levels 4-6).[33] This applies to small spin-outs from academia, which cannot afford initial outlay without support. In several fields, such as crop protection and manipulation, financial support is lacking to develop the results of basic research into new products, and the findings are effectively lost. Additional funding for translation sciences is needed to address these issues.

2.13 Some UK technology faces significant barriers to development. For instance, to apply for funding from Innovate UK, or funding bodies such as the Wellcome Trust, small and medium-sized enterprises (SMEs) must make the application and provide support (in cash or in kind) for the project. However, while they may have the vital IP, most SMEs do not have the necessary resources. Without major support from an investor, the potential of the IP may be lost. Addressing these seed funding barriers in order to support them in attracting funding, or bridging initial phases could help with the development of their technology. The concept of patient capital is highly relevant in this area also.

2.14 Short-term funding can be both unproductive and unhelpful to research, and availability of longer term strategies from funding bodies could bring real advantages. For example, in agriculture and related subjects, funding for long-term studies is needed as research can take several years and relies on long-term curation of plant collections. Recent initiatives from the MRC, EPSRC and BBSRC have offered funding for projects lasting 1-2 years, meaning that personnel must begin applying for the next grant or their next job halfway through the project.

3) What can be done to ensure the UK has the necessary skills and manpower to build a world class life sciences sector, both within the research base and the NHS?

3.1 Skills gaps

Identifying skills gaps is important for researchers across the academic, industrial and public service communities. In 2014 the BBSRC and MRC, in collaboration with the RSB, reviewed vulnerable skills and capabilities in the UK bioscience and biomedical research base.[34] The report highlighted that skills gaps exist in many areas, including: interdisciplinarity, maths, statistics, computation, physiology, pathology, microbiology, agriculture and food security. The report also indicates several hurdles to translational research at the clinical interface, such as: a reduction in industry support for clinical trials, the lack of career

[33] The UK Plant Sciences Federation is developing a Roadmap for Plant Sciences to consider this and other challenges. https://www.rsb.org.uk/ukpsf

[34] BBSRC and MRC review of vulnerable skills and capabilities. https://www.mrc.ac.uk/documents/pdf/review-of-vulnerable-skills-and-capabilities/

structure, and time and regulatory constraints placed on clinicians, restricting the opportunities to pursue research.

3.2 A 2014 report by the UK Plant Sciences Federation examined skills shortages within plant sciences – a strategically important capability for the UK – identifying demand for skills in plant physiology, plant pathology, field studies, horticultural science, crop science, taxonomy and identification.[35] The lack of training opportunities in these areas, as well as a lack of focus on plant science in the school curriculum, likely contributes to the problem. More information about skills gaps in STEM and our recommendations to address them can be found in the Royal Society of Biology's response to the House of Commons Science and Technology Committee inquiry into closing the STEM skills gap.[36]

3.3 The Life Sciences Industrial Strategy Report urges a gap analysis and skills action plan.[37]

3.4 In medicine, gaps in knowledge and skills affect both the research base and clinical practice. For example, current understanding of personalised medicine and of the pharmacokinetics and pharmacodynamics of drugs in common usage remains sub-optimal. We do not know how the effects of many drugs vary with the gender, age, or the genetic traits of patients, so it is unlikely that we are using them in the most effective and efficient way in terms of patient outcomes or financial and time cost; the recent debate on duration of antibiotic courses is an example of this.[38]

3.5 Vital expertise in areas of medical microbiology – such as mycology, the study of fungi – is at risk of disappearing. The news that over 200 patients in England were recently infected with a drug-resistant fungus underscores the importance of specialist knowledge in this field.[39] Concern has also been highlighted over the need for skilled researchers to address the high prevalence and cost of mental health and nervous system disorders in the UK. Microbiologists require a broad palette of skills: it is imperative that the introduction and use of new techniques, such as whole genome sequencing, are not seen as a replacement for fundamental skills; classical skills should be viewed as complementary. As specialisation renders training in whole-body integrative physiology less common, a consequence may be that it becomes more difficult to predict systemic effects of new treatments. Opportunities for cross-disciplinary training provide an important route to adjust to this trend.

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[35] UK Plant Science: Current status & future challenges. https://www.rsb.org.uk/images/pdf/UK_Plant_Science-Current_status_and_future_challenges.pdf
[36] The Royal Society of Biology response to an inquiry into closing the STEM skills gap. http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/science-and-technology-committee/closing-the-stem-skills-gap/written/45123.pdf
[37] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/640696/life-sciences-industrial-strategy.pdf p63
[38] LeSPAR responds to BMJ publication on antibiotic course duration . https://www.rsb.org.uk/news/14-news/1796-lespar-responds-to-bmj-publication-on-antibiotic-course-duration
[39] Japanese fungus spreading in UK hospitals. http://www.bbc.co.uk/news/health-40934190

3.6 Skills in business development and entrepreneurship are important to developing a world class life sciences sector, but young scientists may face several barriers to developing these skills. There is a huge amount to learn in becoming a scientific entrepreneur that is not catered for in the culture of most universities. Younger scientists considering a career in an area of translational science, for example those contemplating commercialising their science via establishing a spin-out company, face additional risks, including the lack of a sustained publication record. There are few schemes that provide business training to young scientists while also allowing them to gather supportive data and develop a business plan. As such, young scientists may be taking a bigger risk in following this type of career trajectory than those who maintain an academic focus. To remedy this, entrepreneurship training could be included in PhD training programmes, and delivered to post-doctoral researchers and early-career scientists. Several universities run enterprise summer schools for postgraduate researchers.[40,41] Support for enterprise fellowships or other flexible schemes to follow on from this training would be helpful. Programmes like Midlands Medici, which offers enterprise fellowships across universities in the Midlands with funding through the Higher Education Funding Council for England (HEFCE), have led to several spinouts.

3.7 Recruitment and upskilling

Developing a skilled workforce requires a commitment to science education, beginning in schools, where many young people have made up their mind about whether they are interested in science before the age of 11.[42] Provision of early, high-quality, one-to-one careers guidance, information about exemplar professionals and the labour market in the curriculum, and encounters for pupils with employers and universities are particularly important for developing future scientists, as are efforts to address perceived barriers to diversity and inclusion regarding the science, technology, engineering and maths (STEM) workforce. It is important that studying life sciences or following technical routes into employment not only provides a strong knowledge base but also develops technical skills and employability; this is supported by the recommendations made in the Wakeham review and by the Government's post-16 skills plan.[43,44]

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[40] University of Birmingham Postgraduate Enterprise Summer School https://intranet.birmingham.ac.uk/as/employability/careers/postgraduate/pgr/pess.aspx

[41] University of Manchester Enterprise Summer School https://mec.portals.mbs.ac.uk/Enterpriseactivities/Enterpriseschool.aspx

[42] King's College London (2013) ASPIRES: Young people's science and career aspirations, age 10-14. http://www.kcl.ac.uk/sspp/departments/education/research/ASPIRES/ASPIRES-final-report-December-2013.pdf

[43] STEM degree provision and graduate employability: Wakeham review. https://www.gov.uk/government/publications/stem-degree-provision-and-graduate-employability-wakeham-review

[44] Post-16 skills plan and independent report on technical education. https://www.gov.uk/government/publications/post-16-skills-plan-and-independent-report-on-technical-education

3.8 Increasing dependence on technology in the work place, manipulation and analysis of big data, and more demanding quantitative elements of undergraduate studies has led to concerns about the uptake of post-16 maths qualifications in those moving on to further study and work within the biosciences. The Smith Review of post-16 mathematics states that three quarters of 16 year olds who achieved an A* - C grade in GCSE mathematics in 2015/16 did not continue with mathematics post-16, and that 61% of biology undergraduates between 2011/12 and 2012/2013 did not have mathematics beyond GCSE.[45] Furthermore, England is one of the few countries where the proportion of students continuing to study mathematics post-16 is less than 20%. With increasing emphasis on mathematics skills in both graduate and non-graduate roles, supporting numeracy skills through core mathematics post-16 will become more important in developing a skilled workforce. Core maths qualifications, studied in addition to A levels, can help bridge the gap between GCSE and undergraduate studies for life sciences students. Schools should be funded and supported in delivering core maths.

3.9 Technical education should be promoted and developed to provide alternative routes to develop skills in the life sciences sector, including apprenticeships and appropriate T-levels- which may provide alternative routes for people to enter higher education. Recognition and support for those following technical routes is important to encourage retention of individuals following this track. One route to this is through increased professional registration of the technical workforce; another may be through defining clear career pathways[46].

3.10 At degree level, undergraduates need to acquire knowledge and skills relevant to employment. Professional bodies can oversee course content and offer accreditation to those meeting strict criteria. To address the skills gaps identified by employers among graduates, the Royal Society of Biology launched its Advanced Accreditation programme in 2012 (with a focus on research and skills achieved during degrees with a placement year or integrated master's year). In 2015, the Society launched its Degree Accreditation programme for standard three-year courses, and four-year courses in Scotland. To achieve Accreditation, universities must provide evidence that courses meet six overarching learning outcomes: direct experience of independent research, technical skill, transferable skills, appropriate understanding of the physical sciences, core and subject specific subject knowledge and greater experience of demonstrating creativity and innovation. Following action by universities during the accreditation process, institutes have increased the physical sciences and maths content of courses, raised standards of final year projects, increased provision and assessment of technical and transferable skills, ensured that core bioscience concepts are included in all courses and have become more aware of the need to promote creative thinking in students; thereby improving the skills and employability outcomes for bioscience students.

[45] Smith review of post-16 mathematics. https://www.gov.uk/government/publications/smith-review-of-post-16-maths-report-and-government-response

[46] Institute of Animal Technology Career pathway for Animal Technologists: http://www.iat.org.uk/pathway

3.11 We need inspirational teachers in schools, colleges and universities to encourage young people to enter careers in the life sciences. The (Teaching Excellence Framework) TEF has the potential to raise the value of teaching in universities and ensuring that higher education teachers are recognised and rewarded for their efforts.

3.12 The push to increase uptake of bioscience subjects needs to be balanced with the recognition that some areas are extremely competitive. **Very few graduates will become principal investigators, for example, and there may be fewer career opportunities in some areas than the number of people encouraged to pursue them. Efforts should be made to ensure appropriate workforce and career planning for future generations of STEM graduates, and enable the necessary routes – for instance, master's courses – that allow transitions between alternative career destinations.** The Royal Society of Biology and its member organisations are supporting career professionals and university staff in enhancing the employability of bioscience students, for example through training events.[47]

3.13 Professional registration provides a route to upskilling the workforce, offering validation for skills, knowledge and experience in the workplace. To achieve registration, applicants must demonstrate their professional competence. Members must engage with and reflect on their continuing professional development, maintaining an annual record, to remain on a register. The Royal Society of Biology offers a number of registers under licence from the Science Council, providing the opportunity for science technicians, scientists, and science teachers to receive recognition and improve their skills.[48] These registers are available to those working across the life sciences including: Registered Science Technician, Registered Scientist, Chartered Scientist, Chartered Biologist and Chartered Science Teacher. Successful members can use post-nominal letters to denote their ongoing achievements. In addition, the Society hosts the Register of Animal Scientists and Animal Technologists, the International Register of Fetal Morphologists, the UK Register for Toxicologists, the Plant Health Professionals Register, and the Qualified Persons Register for those working in the pharmaceutical industry.

3.14 <u>Attractiveness of science careers</u>
Many highly capable people may be deterred from pursuing particular careers in medicine or academic science by a career pathway that can entail many years of short-term jobs, relatively low pay, relocation and uncertainty before obtaining a stable job, due to the short term nature of some contracts and the lack of permanent academic posts. This can be especially difficult for young couples or families. Long-term funding in the UK is rare, and in some fields, less than a tenth of grant applications are successful; these factors likely discourage post-graduates and early career researchers from continuing in academic science, meaning that

[47] Enhancing the employability of biosciences students. https://www.eventbrite.co.uk/e/enhancing-the-employability-of-bioscience-students-tickets-36539346168
[48] Royal Society of Biology: professional registers. https://www.rsb.org.uk/careers-and-cpd/registers

skills are lost. Diminishing pension benefits may also reduce the attractiveness of a career in science. These are not easy problems to solve, though more stable funding, especially for early career researchers may help. Longer-term employment for university technicians, lab managers and administration support would also ease the burden on academic scientists at all levels and help to avoid erosion of the skills-base needed to operate in complex technologies.

3.15 Harnessing international opportunities
Enabling movement of skilled workers between countries helps to reduce skills gaps, and needs to be retained as far as possible after Brexit. A free flow of people from Europe and beyond (including North America) helps to deliver business and technical leadership. In scientific research, the UK benefits from the opportunity for its researchers (especially at post-doctoral stage) to move abroad and return with new skills. Marie Skłodowska Curie Fellowships are designed to facilitate international movement of early-career researchers, developing skills and experience.[49] The current EU Horizon funding programmes[50] allow for researchers to work in multi-disciplinary fields and enable exchange and networking between associated countries. The Government should aim for the fullest possible participation in EU funding schemes such as Horizon2020 and the Marie Skłodowska-Curie actions.

3.16 The UK also benefits from attracting international talent, but this has become significantly harder since the UK Government committed to exiting the European Union. There are many examples demonstrating that international researchers feel less welcome and so are choosing to leave the UK or to not work here in the first place. For example, among the 5,000 Spanish researchers in the UK, a survey circulated in late 2016 found that 30% had already changed their plans as a result of the Referendum, and a further 43% were waiting for negotiations to begin before making a decision.[51] Although there are polls showing considerable support among the British public for researchers coming to the UK,[52,53] more must be done to incentivise the influx of international talent, for example through removing student numbers from immigration statistics. Allowing foreign graduates trained in the UK to remain and use their skills in this country will benefit the research base, as well as linking in to academic and industrial contacts around the world. Further, retention of workers in the UK who are currently considering relocation because of Brexit is a concern, with the danger of a 'brain drain'.

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[49] Marie Skłodowska-Curie Actions: individual fellowships. http://ec.europa.eu/research/mariecurieactions/about/individual-fellowships_en

[50] Horizon 2020. The EU Framework Programme for Research and Innovation. https://ec.europa.eu/programmes/horizon2020/

[51] The future of Spanish researchers in the UK, conditioned by Brexit. http://sruk.org.uk/wp/wp-content/uploads/2017/07/20170324-brexit-press-release_web.pdf

[52] New ComRes poll: majority of British public would like to see the same number or more international students. http://www.universitiesuk.ac.uk/news/Pages/majority-of-british-public-would-like-to-see-same-number-or-more-international-students.aspx

[53] Immigration: keeping the UK at the heart of global science and engineering. Report by the Campaign for Science and Engineering (CaSE), 2016. http://www.sciencecampaign.org.uk/resource/caseimmigrationreport2016.html

3.17 To be world leading, researchers need to interact with the rest of the world. Many principal investigators at UK universities do not have the funds to travel to as many international conferences and meetings as their counterparts from other countries, so that links and opportunities are missed.

4) How does the UK compare to other countries in this sector, for example Germany and the United States?

5) What can be learnt from the impact of the 2011 UK Life Sciences Strategy? What evidence is there that a strategy will work for the life sciences sector? How can its success be measured against its stated objectives?

5.1 It is important to recognise that 'Life Sciences' spans a range of disciplines extending beyond pharmaceuticals and healthcare (see Q1). A new Life Sciences Industrial Strategy should also consider other areas, for instance: animal and plant health, biomanufacturing, microbiology, synthetic biology, industrial biotechnology, biofuels, agriculture and crop improvement, among others. The Strategy should also address the environment, to ensure that advances are not achieved at a cost to the Earth's life-support systems. [54] This link between human health and wellbeing and the health of natural systems is increasingly recognised, and is encapsulated in the concept of 'planetary health'.

5.2 Communication is a vital and too frequently overlooked area that the Strategy should consider. It should consider how to ensure productive and ongoing communication between research scientists, innovators, entrepreneurs and end-users, such as clinicians and farmers, and the public, to enable informative discussion.

5.3 The Strategy should recognise and address a problem with strategic funding models, namely that they are not always appropriately phased so that the right resource goes to the right place at the right time. For instance, while the NHS is uniquely positioned to assist the transfer of innovation from the research lab to the clinic, with a large population of accessible patients to provide samples for research activities and subjects for clinical trials, research groups may struggle to be able to access these resources at the right time.

5.4 Criteria to measure the success of the Strategy will vary between areas of the life sciences. In the medical field, measures of success could be the extent to which it can establish UK manufacturing activity for the next generation of instrumentation, medicines and of course in terms of ill-health avoided; this is a long-term aim that will require support for basic research (including in biology, biophysics and bioengineering). Within health, all areas of research are becoming more expensive and sophisticated, but the UK needs to improve capacity to develop new

[54] Safeguarding human health in the Anthropocene epoch: report of The Rockefeller Foundation–Lancet Commission on planetary health. http://www.thelancet.com/commissions/planetary-health

technology. Instruments are now mostly imported, even where they are developed from UK research – for instance, microscopes in analytical medicine, therapeutics and diagnostics using monoclonal antibodies, diagnostic instruments for body fluids, and MRI instrumentation- which is based on UK magnet technology.

6) Does the strategy contain the right recommendations? What should it contain/what is missing? How will the life sciences strategy interact with the wider industrial strategy, including regional and devolved administration strategies? How will the strategies be coordinated so that they don't operate in 'silos'?

6.1 The strategy provides recommendations that address many areas of concern. These include recommendations to:

- increase research funding (including for fundamental, translational and interdisciplinary research)
- support the investment of patient capital
- create a migration system that is effective for research
- develop clusters of expertise
- reduce skills gaps in maths, computing, statistics, interdisciplinarity, pathology and pharmacology
- embed competencies in commercial acumen and entrepreneurship at degree and PhD level
- provide technical pathways of education
- support further collaboration between researchers and end-users
- address the shortage of STEM teachers.

6.2 Many of these recommendations, if implemented, would provide general benefit to the UK bioscience community. As mentioned previously, the focus of the strategy on healthcare dictates that opportunities relating specifically to other areas of bioscience – including areas associated with strategically important capabilities, such as agriculture and food sustainability– are not offered; additional strategies should be considered for these areas (see Q1).

6.3 Further, the strategy does not discuss a number of important areas, for instance: difficulties that deter or prevent the protection of intellectual property among academic researchers (see Q2), the importance of providing opportunities for upskilling and to support continuing professional development among the life sciences workforce, and clarity about processes for allocating research funding under the strategy.

7) What opportunities for small and medium sized enterprises (SMEs) are there/should there be in the strategy? How can they be involved in its development and implementation?

8) Where should the funding come from to support the implementation of the strategy?

9) How do the devolved administrations and city regions fit into the strategy? Scotland has its own life sciences strategy, how will the two interact?

9.1 Concentrating large research communities around academic centres of excellence can enable hubs to flourish, as examples from the US show (for instance in Boston, or the California Bay Area). However, efforts should not be restricted to the southeast of England; there is much underdeveloped talent and expertise elsewhere in the UK, and any future strategy should capitalise on and support that, in addition to the more established hubs.

9.2 There may be potential benefits from more close research collaboration with RCUK/UKRI by the devolved agriculture agencies (for example Rural Affairs, Food and the Environment Strategic Research in Scotland[55]), both for basic and translatable science, through avoiding duplication and gaining added value across the borders. The interactions between arms-length bodies across borders, such as the Food Standards Agency with Food Standards Scotland, and Public Health England with Health Protection Scotland may provide a model.

9.3 The Science and Innovation Audits (SIAs) commissioned by BEIS provide regional reviews of the strengths in science and innovation within their regions, which should form the basis of future investment planning.[56]

10) How can public procurement, in particular by the NHS, be an effective stimulus for innovation in the Life Sciences Sector? Can it help support emerging businesses in the Life Sciences sector?

11) How can the recommendations of the Accelerated Access Review be taken forward alongside the strategy? Will the recent changes to the NHS England approval process for drugs have a positive or negative effect on the availability of new and innovative treatments in the NHS? How can quick access to new treatments and the need to provide value for money be reconciled?

12) How can collaboration between researchers and the NHS be improved, particularly in light of increased fiscal pressures in the NHS? Will the NHS England research plan help in this regard? How can the ability of the NHS to contribute to the development of and adopting new technology be improved?

13) Who should take responsibility for the implementation of the Life Sciences Industrial Strategy and to whom should they be accountable? What should the UK Government's role be? What should the role of the academic, charitable and business sectors be?

13.1 Government, business and the academic and charitable sectors will all have a part in implementing the Strategy. The Government should have

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[55] Rural Affairs, Food and the Environment (RAFE) Strategic Research. http://www.gov.scot/Topics/Research/About/EBAR

[56] Science and innovation audits: Wave 1 summary reports. https://www.gov.uk/government/publications/science-and-innovation-audits-first-wave-reports

a broad role, which will involve supporting research, enabling movement of scientists between the UK and other countries and ensuring that some of the benefit from commercialising UK innovation returns to UK research. Government also needs to protect the public interest and ensure the strategy benefits all of the people of the UK.

13.2 Within Government, a 'champion' could help to progress the strategy. This person would need access to significant funding and authority to go across departments, as well as to develop links with outside organisations and companies.

13.3 Because of the social importance of decisions to be made, it would be prudent to involve others with a stake in the strategy in its oversight, for instance: organisations representing consumer and patients' interests, learned societies, bodies with expertise in ethics, as well as the agricultural sector, others in business, the education sector (including university-based academics) and other charitable organisations. Effective and early consultation among these groups will help to offset some of the dangers and to realise the benefits that are latent within the strategy.

13.4 Learned societies can offer evidence-based scrutiny and recommendations on the support needed for particular areas of science. In addition, learned societies are important networks through which the academic, public and industrial sectors can form new collaborations.

14) What is the role of companies within the sector, particularly the large pharmaceutical companies, in the implementation of the strategy? How are they accountable for its success?

14.1 Companies, large and small, are a vital avenue to deliver some outputs and benefits of research to the public, and contributing to the economy through taxation and employment. Companies also receive substantial benefits from the public sector: infrastructure, an educated workforce, and the origin of most high-risk, early-stage research in the university sector, supported by public money. It should not be expected that the interests and priorities of commercial entities will align with those of taxpayers, a healthy tension between the private and public spheres can produce outcomes that benefit the UK as a whole. One aim for the strategy should be to stop the exodus of large companies from the UK – there have been prominent losses in the pharmaceutical sector. It is essential that the Strategy achieves a high level of engagement with life science companies across all relevant industries, and across all sizes of company. Other industries, including those in the agri-tech and agri-food sectors, among others, contribute to the push and pull on public wellbeing, to the public purse and to the research and technology development ecosystem.

14.2 Companies can help by engaging with Government, educators and trainers to ensure that the skill requirements of industry are well signalled to the public, to educators and to agencies. Companies can also help through partnerships that build on successful public research, bringing together complementary expertise; such partnerships should be supported. Research institutes provide hubs that bring together academic and industrial partners. For instance, Bayer[57] and Syngenta[58] have entered into separate partnership agreements with Rothamsted Research, Hertfordshire, aiming to bring fundamental advances in crop science to the market. Large companies can also support research and build collaborations with research groups, for example through CASE partnerships for PhD funding.[59] However, some of our members have suggested that a greater financial contribution to CASE studentships from the industrial partners, in line with that provided by charitable foundations such as the Wellcome Trust, would improve projects, and increase their significance to the supporting company.

14.3 The responsibility should not be limited to larger organisations; SMEs could also have a role in implementation of the Strategy, so that all views from the sector are represented. As many SMEs are spin-outs from the academic sector, their inclusion brings in this voice also.

15) Does the Government have the right structures in place to support the life science sector? Is the Office of Life Sciences effective? Should the Government appoint a dedicated Life Sciences Minister? If so, should that Minister have UK-wide or England-only responsibilities?

15.1 Current Government structures could do more to support the life sciences. The Office of Life Sciences has a complex structure, divided between Government departments and involving several ministers. Its direction is unclear, as is the position of fundamental research in life sciences, and its level of priority. The relationship of the Office with the system of departmental Chief Scientific Advisors and with the Government Chief Scientific Advisor is unclear. Further, the current focus on health excludes the broader biosciences. The Office of Life Sciences could have improved links with other relevant Government departments and Ministers, for instance, with Defra to coordinate on innovation in agri-food, and with the Minister for Universities and Science, while maintaining links with BEIS and the Department of Health.

15.2 Appointing a Minister with overall responsibility for the life sciences could improve this situation, and create a position with overall responsibility for delivering the new Strategy. The Life Sciences Strategy should be UK-wide, with delivery responsibilities reflecting this, since, despite local priorities, many issues cross boundaries. A Minister should help to coordinate all relevant stakeholders and skills, work together with the

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[57] Smart revolution promises sustainable crop protection in the age of digital agriculture. https://www.rothamsted.ac.uk/news/smart-revolution-promises-sustainable-crop-protection-age-digital-agriculture

[58] Rothamsted and Syngenta announce a multi-million pound scientific partnership to develop high yielding, environmentally sustainable wheat. https://web.archive.org/web/20150321000339/https://www.rothamsted.ac.uk/news/rothamsted-and-syngenta-announce-multi-million-pound-scientific-partnership-develop-high

[59] CASE studentships – Collaborative/Industrial placements. http://www.bbsrc.ac.uk/skills/investing-doctoral-training/case-studentships/

Research Councils, Innovate UK, and UKRI, and demonstrate to the Treasury and Cabinet that science funding is an investment, not a cost, with substantial returns to the Treasury from research grants, in addition to those benefits that arise from the research itself.

15.3 To make the most of this opportunity, a clear definition of 'life sciences' is needed, and we would recommend a broad definition (as outlined in the response to Question 1). It is important to remember that agriculture and the environment are also part of the broader life sciences, and supermarkets and food companies have a big influence in this sphere. There is already a position of Secretary of State for the Environment, Food and Rural Affairs, with whom a Minister for Life Sciences would need to work closely. This brief has changed hands frequently in recent years, resulting in policy shifts. Oversight of the plant-based bioeconomy is currently divided between Defra and BEIS, with separate 'silos' of knowledge between agriculture, food, industrial biotechnology and biofuels. A new ministerial position could help to link these areas, though it is important to bear in mind that agriculture and the environment are devolved matters.

15.4 A durable and ambitious Ministry could be of considerable benefit to the diverse and rapidly expanding life sciences sector and through this to the UK as a whole.

16) What impact will Brexit have on the Life Sciences sector? Will the strategy help the sector to mitigate the risks and take advantage of the opportunities of Brexit?

16.1 Brexit has far-reaching implications for the Life Sciences sector, and there are significant concerns within the community that need to be addressed. **Among other concerns is unease that the Department for Exiting the European Union currently lacks a Chief Scientific Adviser, as does the Department for International Trade.[60]**

16.2 UK researchers have been highly successful in securing EU funding to supplement the UK Government's investment in science. Total investment in UK science will be significantly reduced following the loss of funding obtained through Horizon2020 and its successors, responsive mode funding provided by the European Research Council,[61] Marie Skłodowska-Curie fellowships[62] (particularly valuable to early career researchers), and the Innovative Medicines Initiative[63].

16.3 The Government should seek to retain the closest possible association with these programmes as part of the Brexit deal, as well as increasing its investment in science. Britain currently spends less on research and development than other countries: roughly 1.7% of GDP, compared with

[60] Chief Scientific Advisers https://www.gov.uk/government/groups/chief-scientific-advisers
[61] European Research Council https://erc.europa.eu/
[62] Marie Skłodowska-Curie actions - Research Fellowship Programme https://ec.europa.eu/research/mariecurieactions/
[63] The IMI http://www.imi.europa.eu/

2.8% in the US and 2.9% in Germany.[64] **The Government should keep the pledge made in the Conservative Party manifesto 2017 to increase investment in R&D to 2.4% of GDP within ten years – meeting the current OECD average – with the longer-term goal of 3%.[65] We strongly urge an accelerated trajectory towards these aims.**

16.4 The UK has also been successful in coordinating EU networks, and has benefitted enormously from close collaboration with scientists and research centres in the rest of the EU. The loss or restriction of access to research facilities in the EU will leave UK scientists isolated, and diminish networking opportunities. Many EU institutions have developed expertise in particular areas, and removing access to these from UK researchers will be detrimental. It is unrealistic to expect the collaborative opportunities we currently enjoy with the EU to be replicated with non-EU partners soon, if at all. Strategic investment in particular areas may be needed where the UK has previously relied on international collaborations to supply necessary expertise.

16.5 UK institutions benefit from the ability to bring in scientists freely from other EU countries, both directly from their expertise, and indirectly through forging partnerships. It is vital we maintain the ability of researchers, scientists and other technical personnel to enter and work in the UK efficiently and effectively. An immigration system is needed that maintains and enhances the UK's ability to attract and retain the best staff and students from a global talent pool. The opportunity for researchers from the UK to live and work abroad, often returning with new skills and collaborations, must also be maintained. The Erasmus programme[66] also offers researchers and students an opportunity to gain new knowledge and skills, as well as to build new networks in other European countries (and vice versa); it is valued and should be protected or replicated. The threat of an uncoordinated departure from the EU is likely to hinder collaboration; already there are reports of scientists working in the UK looking to leave – both those of EU and UK origin and indeed non-EU nationals – raising the prospect of a further brain-drain to the US, Germany, China, and other countries.

16.6 The UK's departure from the European Union is likely to result in the relocation of EU Reference Laboratories hosted in the UK – for example, the Reference Laboratories on transmissible spongiform encephalopathies (e.g. BSE) and avian influenza housed in the UK Animal and Plant Health Agency.[67,68] Losing these Reference Laboratories, and access to those hosted in other EU member states, is likely to entail a loss of expertise and specialist knowledge. Many UK

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[64] UK election: science spending pledges overshadowed by Brexit. https://www.nature.com/news/uk-election-science-spending-pledges-overshadowed-by-brexit-1.22067
[65] Forward together: the Conservative and Unionist party manifesto 2017. https://s3.eu-west-2.amazonaws.com/manifesto2017/Manifesto2017.pdf
[66] Erasmus Programme http://www.erasmusprogramme.com/
[67] TSE-LAB-NET: TSE European Union Reference Laboratory https://science.vla.gov.uk/tse-lab-net/
[68] FLU-LAB-NET: An EU funded Avian Influenza programme https://science.vla.gov.uk/flu-lab-net/

companies in the life sciences sector have subsidiaries or close links with companies in the rest of the EU. For instance, plant breeding companies have operations in warmer parts of the EU to shorten breeding programmes. Plant breeding is an application of life sciences on which we depend to maintain an adequate food supply, and it is vital that Brexit negotiations accommodate the operations of these systems.

16.7 Regulations in many areas will need to be aligned with the EU to avoid both restrictions on exports and the UK becoming a niche market for products manufactured abroad. For instance, this applies in the case of clinical trials, approval of medicines and the safety of products, supplements and food items. Failure to maintain an adequate degree of regulatory alignment could harm the development of SMEs, further the loss of multinationals, and make the UK unattractive to foreign businesses.

17) How should the regulatory framework be changed or improved after Brexit to support the sector?

17.1 Any changes to regulations following the Withdrawal Bill should be made only with full and appropriate community consultation and with parliamentary scrutiny. Proposed changes should uphold standards for the people and the natural environment of the UK, rather than weakening them. The EU has achieved many successes in limiting the effects of irresponsible commercial exploitation, including protection of workers' rights, the environment and animal welfare, and limiting antibiotic use in raising food animals; there is no indication that the referendum vote aimed to weaken these protections. Experience shows that, in the absence of strong oversight, administration change can invite development of a culture which is business-friendly to the extent of forgetting the importance of enforcing limits on what it can do. Business interests that lobby for a weakening EU regulation, or an inclination to do so within Government, must be counterbalanced by appropriate regulation. The Withdrawal Bill must introduce appropriate governance mechanisms to replace the supervisory and oversight influence of the European Commission.

17.2 The fundamental principles of providing evidence of benefit and risk for medicines will continue to apply across the spectrum and thus ongoing cooperation in EU regulatory frameworks, and regarding data collection and sharing, should be considered as part of the future arrangements. UK standards must mirror those of our major current and future markets, as far as that is possible. To comply with different standards in the EU and UK would be an additional burden on UK businesses.

17.3 In some areas, however, improvements to regulation are possible. For instance, Brexit presents an opportunity to rethink the regulatory framework for the latest plant breeding methods, including the use of genetic modification (GM). This would enable scientists and farmers to use more of the available tools to produce food that has safe and beneficial characteristics in terms of nutrition, yield, or environmental impact. Changes to regulation in this area could reinvigorate science in biotechnology and crop protection, although internationally-harmonised criteria would be required to facilitate trade.

17.4 As an example of a currently-evolving regulation the Nagoya Protocol on Access and Benefit Sharing (ABS) has broad implications that are supported in principle, but in relation to which some specific areas of concern have arisen for our members. Proposed elements of the regulation in relation to digital genetic sequence data may be difficult to implement, and therefore to comply with. There is concern that aspects of the Nagoya Protocol could limit researchers' sharing of information and genetic sequence data, on a country by country basis, depending on the provider country's ABS legislation. Continued stakeholder consultation and careful interpretation of the Nagoya Protocol (and other pertinent legislation) will be required.[69]

17.5 Regulations that enhance establishment and protection for UK innovation would help to improve the opportunity to grow UK business. However, such approaches to a UK-specific regulatory environment will be, of necessity, likely protectionist and unlikely to be sustainable.

18) To what extent should the UK remain involved with and contribute to agencies such as the EMA post Brexit?

18.1 There has been a global effort to harmonise medicines regulation among regulators in different regions, e.g. the EMA, FDA (US Food and Drug Administration) and PMDA (Japanese Pharmaceuticals and Medical Devices Agency) to ease and speed the cost of medicines discovery and development. At present the UK is an integral part of European regulatory frameworks. Our membership has helped to drive effective regulation to speed up patients' access to new medicines, through schemes such as PRIME.[70]

18.2 **Post-Brexit, the UK should remain committed to these efforts, and to the EMA, to the closest extent possible. Failure to cooperate very closely with the EMA would likely see significant restrictions quickly imposed on exports to the EU – a major market. Non-cooperation with the EMA would also require the establishment of a UK equivalent to approve new medicines, resulting in a costly duplication of effort;** the findings – and hopefully the standards – of the review process for medicines should not change according to the regulatory authority.

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[69] Response from the Royal Society of Biology to Defra's request for views and relevant information on potential implications of the use of Digital Sequence Information (DSI) on genetic resources for the three objectives of the Convention on Biological Diversity (CBD) and for the objective of the Nagoya Protocol on Access and Benefit Sharing (ABS).
https://www.rsb.org.uk/images/article/policy/RSB_response_Defra_call_for_comment_on_DSI_and_Nagoya_protocol.pdf

[70] PRIME: priority medicines.
http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000660.jsp

18.3 Post-Brexit, the UK should also seek to be involved in IP agreements, such as the Unitary Patent.[71] Continued support for this is essential, to reduce the cost of protecting inventions made in UK academia and business. It is currently significantly faster and cheaper to obtain a patent in the USA, for example, than in Europe, despite a similar population size. The cost of validating a patent in each European nation state is prohibitive for universities and small businesses.

18.4 Life scientists in the UK also contribute significantly to EU-level agencies other than the EMA. The UK is an important source of expertise and advice for the European Centre for Disease Control and Prevention (ECDC) and the European Food Safety Agency (EFSA). It is important to note that these agencies operate across life science disciplines, drawing upon expert knowledge of human health, animal health, microbiology, and food- and agriscience, to name a few.

18.5 For example, monitoring and combating diseases such as SARS, Ebola, and international outbreaks of lethal *E. coli* (such as the Shiga toxin-producing *E. coli* O104:H4) at the EU level is the responsibility of the ECDC. The UK supplies and receives information on infectious diseases to the ECDC at regular intervals, and many UK citizens are employed by this organisation. **Care must be taken to ensure that the flow of information to and from the ECDC continues after Brexit.** Likewise, food safety at the EU level is the responsibility of EFSA. As a significant proportion of food consumed in the UK is imported, not just from EU Member states but also from countries out with the EU, it is vital that the safety of such foods continue to be assured. **Many UK citizens are either employed by EFSA, or are members of EFSA expert panels, and play a significant role in contributing to food safety and to animal health. It is vital to the UK that such co-operation continues.**

The Society welcomes the Committee's consultation on the Life Sciences Industrial Strategy. We are pleased to offer these comments, which have been informed by specific input from our members and Member Organisations across the biological disciplines (Appendix A). The RSB is pleased for this response to be publicly available.

20 September 2017

Appendix A: Member Organisations of the Royal Society of Biology

Full Organisational Members
Academy for Healthcare Science
Agriculture and Horticulture Development Board
Amateur Entomologists' Society
Anatomical Society
Association for the Study of Animal Behaviour

[71] Unitary patent. https://ec.europa.eu/growth/industry/intellectual-property/patents/unitary-patent_en

Association of Applied Biologists
Bat Conservation Trust
Biochemical Society
British Andrology Society
British Association for Lung Research
British Association for Psychopharmacology
British Biophysical Society
British Crop Production Council
British Ecological Society
British Lichen Society
British Microcirculation Society
British Mycological Society
British Neuroscience Association
British Pharmacological Society
British Phycological Society
British Society for Cell Biology
British Society for Developmental Biology
British Society for Gene and Cell Therapy
British Society for Immunology
British Society for Matrix Biology
British Society for Medical Mycology
British Society for Nanomedicine
British Society for Neuroendocrinology
British Society for Parasitology
British Society for Plant Pathology
British Society for Proteome Research
British Society for Research on Ageing
British Society of Animal Science
British Society of Plant Breeders
British Society of Soil Science
British Society of Toxicological Pathology
British Toxicology Society
Daphne Jackson Trust
Drug Metabolism Discussion Group
Fisheries Society of the British Isles
Fondazione Guido Bernardini
GARNet
Genetics Society
Heads of University Centres of Biomedical Science
Institute of Animal Technology
Laboratory Animal Science Association
Linnean Society of London
Marine Biological Association
Microbiology Society
MONOGRAM – Cereal and Grasses Research Community
Network of Researchers on Horizontal Gene Transfer & Last Universal Cellular Ancestor
Nutrition Society
Quekett Microscopical Club
Royal Microscopical Society
SCI Horticulture Group
Science and Plants for Schools

Society for Applied Microbiology
Society for Experimental Biology
Society for Reproduction and Fertility
Society for the Study of Human Biology
Systematics Association
The Field Studies Council
The Physiological Society
The Rosaceae Network
Tropical Agriculture Association
UK Environmental Mutagen Society
UK-BRC – Brassica Research Community
University Bioscience Managers' Association
VEGIN – Vegetable Genetic Improvement Network
Zoological Society of London

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BASIS Registration Ltd.
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Ethical Medicines Industry Group
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Wessex Water
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