Royal Society of Biology response to the Science and Technology Committee of the Commons' inquiry on Brexit, Science and Innovation: Preparations for a No - Deal

January 2019

Executive summary

- A no-deal Brexit has the potential to hinder research and development in the UK and act against Government's ambition to achieve a target of spending on R&D equal to 2.4% of GDP by 2027.

- The prospects for UK science depends significantly on the eventual bilateral agreements reached with the European Union. Below, we briefly outline needs of the UK bioscience sector and vital aspects of future collaborations with the EU.

- As we[1] and others[2] have warned previously, the attractiveness and success of the UK as an R&D powerhouse relies on developing, welcoming, and retaining national and international talent[3], whose availability is a key reason for national and international business to locate and invest in the UK, together with access to specialised R&D knowledge and infrastructure[4].

- For both the UK academic and industry R&D sectors a key concern is that access to EU funding, cooperation with researchers and businesses across EU member states; the sharing of material, products, knowledge and data; and the advantages of regulatory alignment are positive characteristics that will be disrupted in case of "no-deal".

- We welcome the Committee's attention to this critical topic although our response is not exhaustive we provide some targeted comments on a no-deal scenario and Government contingency planning.
    - A no-deal scenario could threaten UK patients' access to medicines supply and put the UK pharmaceutical R&D sector at a position of disadvantage relative to its European counterpart.

[1] RSB response to the Science and Technology Committee of the Commons Brexit: science and innovation Summit inquiry (February 2018), summary. Page 1 https://www.rsb.org.uk/images/article/policy/RSB_response_to_HoC_STC_Brexit_science_and_innovation_Summit_inquiry_for_submission.pdf

[2] Royal Society, (2018). "No-deal" is a bad deal for science. https://royalsociety.org/~/media/policy/Publications/2018/royal-society-brexit-no-deal-factsheet.pdf

[3] There are 206,870 academic staff working in the UK. 17% (35,920) of Academic staff working in the UK HEIs are non-UK EEA nationals. https://royalsociety.org/~/media/policy/projects/brexit-uk-science/uk-research-eu-people-june-2018.pdf

[4] Vallance Patrick (2018). "Government target of 2.4% spend on R&D – what is the best way to achieve Government's target of spending of GDP on R&D by 2027?" the Foundation for Science and Technology debate. Presentation slide 9 http://www.foundation.org.uk/Events/pdf/20181017_Vallance.pdf

There is no contingency plan to offset this and only partial measures have been put in place by Government to avoid a crisis of medicine supply.

- We anticipate disruption and delays in data and knowledge sharing between the UK and EU in the field of environmental monitoring (e.g. fisheries) and biosecurity. Contingency plans look at the immediate future but effective policies can only be implemented as part of longer term agreements with our neighbouring EU countries.
- In a no-deal scenario, delays and additional bureaucratic burden will impact the movement of animals and biological material. In order to avoid negative consequences for animal welfare and ongoing research projects, contingency plans must require sufficient resources and capacity to be allocated. At this stage it is difficult to foresee whether severe disruption will be successfully avoided.
- Another sector of the bioeconomy that will be negatively impacted is commercial plant breeding. Plant breeding R&D industries could suffer from barriers to trade, protection and marketing imposed by Brexit, while the UK food sector could suffer from reduced choice of crop variety, and slower access to new varieties than competitors on the continent.

1. Background: The Royal Society of Biology

1.1. 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.

1.2. The Society welcomes the opportunity to comment through the Committee's inquiry on Brexit, Science and Innovation: Preparations for a No-Deal. We are pleased to offer these comments, which have been informed by specific input from our members and Member Organisations across the biological disciplines. Our Member Organisations are listed in the Appendix.

2. The impact of a 'No-Deal' Brexit scenario on the biosciences

2.1. In a No-Deal Brexit scenario, as in any scenario which affects how the UK collaborates internationally through science and innovation to benefit society, the UK must maintain a stable, attractive, welcoming environment for researchers and businesses. Such an environment must provide efficient and effective access to EU and global infrastructure, funding, skills and expertise at every level and stage of the research and development (R&D) cycle, from fundamental research to translation and application for societal benefit, in order to promote national and international scientific collaboration and productivity.

2.2. There are central components of a stable, attractive, welcoming environment for researchers and businesses. For the bioscience community, these translate into fundamental needs that are of vital importance to achieve our potential to contribute to the UK's international standing, provide excellent return on public investment, deliver benefit to society, and contribute to the objectives of the Government's Industrial Strategy.

2.3. In summary, these needs are:

- Maintenance of a skilled scientific workforce – capable of delivering research and industrial output, education and training - through efficient and consistent systems to attract and recruit skilled and qualified people to move to and from the UK and EU.
- Active and clear advice and information from Government, through the Brexit process and beyond, in relation to the rights of EU citizens in the UK, visa schemes, and arrangements for travellers.
- Continued access to EU budgets, frameworks, infrastructure and partnerships, including EuropeAid, Horizon 2020 and its successor programmes, and relevant funding programmes and frameworks[5]. If the UK loses access to any/all EU budgets, there should be alternative funding regimes created within the UK. Furthermore, there must be a sustainable future for UKAid, with an appropriate transition so that aid recipients are not disadvantaged.[6] Government's underwrite guarantee to cover successful bids to certain EU programmes in case of no-deal, such as Horizon 2020 and Erasmus+ grant programme, is welcome and a necessary mitigating measure. However, other prestigious research grants, such as the European Research Council (ERC) grants and some Marie Sklodowska-Curie Actions, which have played a significant part in supporting academic research in the UK, will not be equally covered by the UK government. It will be essential that alternative arrangements with the EU or additional UK-based funding schemes are proposed and evaluated as a matter of urgency to make up for the loss of these grants.
- A fiscal environment that encourages EU and global investment in UK R&D is essential to continue to encourage private investment, this will contribute significantly towards the Government's target of 2.4% of GDP invested in UK R&D by 2027.[7] The UKs strong bioscience base has been an important encouragement to inward investment.[8]
- Support and mutual recognition for necessary common standards, frameworks and professional qualifications to enable collaboration and trade with the EU, with divergence only considered following detailed community consultation.

2.4. We describe these needs in more detail in many of our recent consultation responses [9] and briefings, and would like to draw the Committee's attention in particular to our responses to the Committee's recent previous inquiries on the *Brexit: Science and Innovation Summit* [10] and on *An*

[5] *For example: SME access to EU financial and "administrative assistance" in accordance with Commission Regulation (EC) No 2049/2005: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005R2049*
[6] RSB response to the Science and Technology Committee of the Commons Brexit: science and innovation Summit inquiry (February 2018), Point 2, page 2; https://www.rsb.org.uk/images/article/policy/RSB_response_to_HoC_STC_Brexit_science_and_innovation_Summit_inquiry_for_submission.pdf
[7] RSB response to the Science and Technology Committee of the Commons inquiry on the balance and effectiveness of research and innovation spending (September 2018): https://www.rsb.org.uk/images/article/policy/RSB_response_to_HoC_STC_inquiry_on_research_and_innovation_spending_submitted.pdf
[8] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/706963/life-sciences-competitiveness-indicators-2018.pdf
[9] RSB consultation responses: https://www.rsb.org.uk/policy/consultations/consultation-responses
[10] RSB response to the Science and Technology Committee of the Commons Brexit: science and innovation Summit inquiry (February 2018): https://www.rsb.org.uk/images/article/policy/RSB_response_to_HoC_STC_Brexit_science_and_innovation_Summit_inquiry_for_submission.pdf

immigration system that works for science and innovation [11], in addition to our recent briefing for Members of Parliament on *Brexit, Science and Innovation* [12].

2.5. In this response, we seek to outline specific concerns flagged by members of the biosciences community, prompted by the current uncertainty around the UK's future relationship with the EU. If not given due consideration as part of the Brexit process, there is a risk that these issues may hinder UK biosciences research, and its translation into societal benefit. Many of these concerns are central to public health and welfare, for example in the production and provision of food and medicines, and as such they should be taken heed of now and receive due consideration in any future changes to international agreements of relevance.

3. The natural environment

3.1. Environmental concerns transcend national borders. Work to monitor, conserve and improve the natural environment involves close collaboration with neighbouring countries. It is important that the UK continues to work with EU countries after EU exit, and a disorderly 'no-deal' Brexit is likely to threaten such collaboration.

3.2. A large proportion of UK fine particulate pollution originates in other countries. This form of pollution is a serious public health risk, with major health and social care costs. In our response to the Government's Clean Air Strategy consultation,[13] the Society stated that "Our ability to reduce levels of this form of pollution partly depends on the measures taken in neighbouring countries in Europe, and may also be affected by production or safety standards of imported products used in the UK."

4. Fisheries

4.1. Post-Brexit, fish stocks will remain limited, and need to be shared; a situation in which the UK and EU set quota limits separately is likely to harm fish stocks, on which many coastal communities depend. In our response to the Environmental Audit Committee inquiry on the 25 Year Environment Plan,[14] the RSB stated that "The UK should address the challenge of how to continue to collaborate as much as possible with the EU on [initiatives such as the EU Marine Strategy Framework Directive], and others regarding shared resources, into the future." As part of this, the UK should aim to maintain active exchange of data, knowledge and expertise with EU networks about the health of fish stock, in order to base any related policy changes on scientific evidence and within a limit set by the maximum sustainable yield.

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[11] RSB response to the Science and Technology Committee of the Commons inquiry on an immigration system that works for science and innovation (June 2018): https://www.rsb.org.uk/images/Policy/RSB_response_to_HoC_STC_An_Immigration_system_that_works_for_science_and_innovation_inquiry_for_submission.pdf

[12] Briefing from the Royal Society of Biology on Brexit, Science and Innovation. *Produced for Members of Parliament attending a House of Commons debate* (September 2018): https://www.rsb.org.uk/images/Policy/HOC_briefing_from_the_RSB_on_Brexit_science_and_innovation_for_release_September_2018_published_version.pdf

[13] Royal Society of Biology response to the Clean Air Strategy consultation (2018): https://www.rsb.org.uk/images/Policy/RSB_response_to_the_Clean_Air_Strategy_consultation_for_submission_for_the_website.pdf

[14] Royal Society of Biology response to the 25 Year Environment Plan inquiry (2018): https://www.rsb.org.uk/images/RSB_response_25_Year_Environment_Plan_inquiry_Submitted.pdf

4.2. Data on fish stocks is currently collected, managed and supplied by EU countries under the Data Collection Framework[15], as established by Regulation (EU) 2017/1004 of 17 May 2017 on the establishment of a Union framework for the collection, management and use of data in the fisheries sector and support for scientific advice regarding the common fisheries policy and repealing Council Regulation (EC) No 199/2008. In order for this data exchange to continue the UK must find future arrangements with the EU.

4.3. Additionally, in order for fisheries to be effectively and collaboratively managed, the UK must remain part of a Regional Fisheries Management Organisation (or RFMO), which is one of several "international bodies formed by countries with fishing interests in the same region or in the same (group of) species. Within these bodies, countries collectively set science-based binding measures such as catch and/or fishing-effort limits, technical measures and control obligations to ensure conservation, as well as fair and sustainable management of the shared marine resources"[16]. Government foresees that it may take up to six months to obtain access to the relevant RFMO if the UK loses EU membership in a 'No-Deal' Brexit scenario[17]. While one consequence of a 'No-Deal' Brexit scenario could entail that UK vessels will no longer have rights to fish in international waters, until a new UK-specific RFMO access is granted, we do not know what the impact for this delay will mean in terms of scientific data sharing and monitoring of fish stocks in UK waters – this gap in data collection and sharing could have long term ramifications.

5. Biosecurity

5.1. Maintaining biosecurity is another area in which collaboration with the EU is vital to protect our environment, economy, food supply chain and health. Unless collaboration can continue, the UK will lose access to expertise, for instance in the European Food Standards Agency (EFSA), as well as immediate access to the EU's information-sharing mechanisms on new biosecurity threats. The Society's response to the 'Brexit: plant and animal biosecurity' inquiry undertaken by the House of Lords European Union Committee,[18] stated that, "Following Brexit, it is vital that close cooperation is maintained between the UK and EU Regulatory Agencies, Reference Networks and Laboratories, enabling the most efficient use of resources and shared expertise, in addition to rapid identification and communication of emerging threats. […] Responsive and well-resourced capacity to deliver biosecurity requirements at UK borders will be needed. This will have to accommodate any checks required by new trading agreements, and to respond to developments, innovations, and threats as they emerge or decline." The Committee's report urged the Government to negotiate continued participation in EU notification and intelligence sharing platforms, and commented that it seemed "doubtful" that the necessary legislative

[15] European Commission. Fisheries sector: data collection: https://ec.europa.eu/fisheries/cfp/fishing_rules/data_collection_en
[16] European Commission, 2018. Facts and figures on the common fisheries policy – Basic statistical data. Page 4: https://ec.europa.eu/fisheries/sites/fisheries/files/docs/body/pcp_en.pdf
[17] Department for Environment, Food & Rural Affairs, 2018. Commercial fishing and marketing of seafood if there's no Brexit deal - Regional fisheries management organisations (RFMOs): https://www.gov.uk/guidance/commercial-fishing-and-marketing-of-seafood-if-theres-no-brexit-deal#european-maritime-and-fisheries-fund-emff
[18] Royal Society of Biology evidence to the Brexit: plant and animal biosecurity inquiry (2018): https://www.rsb.org.uk/images/RSB_response_to_the_HoL_EU_EESC_inquiry_Brexit_plant_and_animal_biosecurity_for_submission.pdf

framework, monitoring, inspection and enforcement mechanisms, staff and IT systems would be in place by the time the UK leaves the EU.[19] This is a matter of great concern.

5.2. An additional related concern stems from the fact that in case of a 'No-Deal' scenario, there will be changes to arrangements for import/export of protected animal and plant species, which come under the Convention on International Trade in Endangered Species of wild fauna and flora (CITES) and are currently implemented and enforced by the EU Wildlife Trade Regulations[20]. Recent discussions at the Convention on International Trade in Endangered Species of wild fauna and flora centred around obtaining simplified procedures for permits and certificates if countries need to share diagnostic samples to monitor and investigate disease outbreaks and emergencies, which require rapid responses. Until now, specimens could be easily moved across the EU but with a 'No-Deal' Brexit permits will be required by UK researchers to share material with the rest of the European Union. Until CITES Conference of Parties adopts the proposed simplified procedure[21], we urge Government to take due consideration and give correspondingly high priority to CITES permit applications for specimens to be shared between designated reference laboratories (included in an approved list by the World Organization for Animal Health and CITES) as part of an emergency diagnostic procedure.

6. The import and export of live animals and some animal products

6.1. Alongside major concerns for food trade and biosecurity, a 'no-deal' Brexit presents great challenges for the transfer of live animals and some animal products (such as germplasm), some of which are used under license in scientific research. The Society has expressed a view on a proposed ban to live animal transport issued by Defra in May 2018[22]. In our response, we highlighted the importance of resource sharing, including certain animal strains and germplasm, for ongoing and upcoming international research projects[23]. Disruption or lack of clarity about the rules and processes that govern transport of animals in the case of a 'No-Deal' scenario has the clear potential to have a negative impact on animal health and welfare as well as the UK biosciences sector and medical and veterinary progress[24].

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[19] House of Lords European Union Committee 2018. Brexit: plant and animal biosecurity: https://publications.parliament.uk/pa/ld201719/ldselect/ldeucom/191/191.pdf

[20] "All CITES species that are currently freely moved and traded between the UK and the EU would require a CITES permit or import/export notification. This would mean movement of all species controlled under CITES between the UK and the EU would need to follow the same processes as those currently in place for movement between the UK and non-EU countries" as stated in the Department for Environment, Food & Rural Affairs, (2019). Government publishes 'No deal' EU exit advice on travel changes for protected animals and plants. https://www.gov.uk/government/news/government-publishes-no-deal-eu-exit-advice-on-travel-changes-for-protected-animals-and-plants?utm_source=30fcdb14-2be1-4453-8bfa-8b51edb59746&utm_medium=email&utm_campaign=govuk-notifications&utm_content=immediate

[21] Convention on International Trade in Endangered Species of wild fauna and flora, (2018). Simplified procedures for permits and certificates: report of the working group. https://cites.org/sites/default/files/eng/com/sc/70/E-SC70-36.pdf

[22] Royal Society of Biology response to the Department for Environment, Food and Rural Affairs call for evidence on controlling live exports for slaughter and to improve animal welfare during transport after the UK leaves the EU, (May 2018): https://www.rsb.org.uk/images/article/policy/RSB_response_to_the_Defra_call_for_evidence_on_controlling_live_exports_for_slaughter_for_submission.pdf

[23] Royal Society of Biology response to the Department for Environment, Food and Rural Affairs call for evidence on controlling live exports for slaughter and to improve animal welfare during transport after the UK leaves the EU, (2018). Paragraph 1.3: https://www.rsb.org.uk/images/article/policy/RSB_response_to_the_Defra_call_for_evidence_on_controlling_live_exports_for_slaughter_for_submission.pdf

[24] Royal Society of Biology response to the Department for Environment, Food and Rural Affairs call for evidence on controlling live exports for slaughter and to improve animal welfare during transport after the UK leaves the EU, (2018). Paragraphs 3.1-3.3: https://www.rsb.org.uk/images/article/policy/RSB_response_to_the_Defra_call_for_evidence_on_controlling_live_exports_for_slaughter_for_submission.pdf

6.2. Up until the day the UK formally leaves the EU, the UK will continue to use the EU-wide Trade Control and Expert System (TRACES), through which importers and exporters can provide health certification and track consignments of live animals, animal products and high risk food not of animal origin[25]. In a 'No-Deal' scenario, the UK is expected to lose access to TRACES on day one of EU Exit. Defra is currently developing a successor system that would replace TRACES called the Import Notification System (INS). With only a short window of time left before the planned UK exit from the EU, preventing disruption to circulation of animals and animal samples will depend critically on the state of progress of this and other contingency systems still under development. A critical aspect related to the replacement of TRACES is that the UK will have to strengthen and/or establish more UK Border Inspection Posts to cope with the transfer of authorities and responsibilities back to the UK. This also implies that the right skilled personnel, who can carry out the necessary health and welfare checks on animals reaching inspection posts, are available and correctly trained. However, there is documented evidence that a great fraction of such skilled personnel [26] (such as veterinarians for example) have originally moved from other EU member states to take up these employment positions within the UK. This is another facet of the widespread concern about EU citizens' rights in the UK after the UK formally leaves the EU, and future arrangements for movement of indispensable professionals into and out of the country.

6.3. Conversely, in relation to the export of animals and animal material for research purposes, it must be stressed that on exit day, in the case of a 'No-Deal' scenario, the UK would need confirmation from the EU of its listing status as a third country as soon as possible, but cannot be certain of the EU response or its timing[27]. Without such listed status there is a risk that exports to the EU could be paused. As is currently the case with export to non-EU countries, after the UK formally leaves the EU, UK exporters would (in this scenario) need an Export Health Certificate (EHC), issued by the Carlisle Centre for International Trade, in order to transport animals and related material to the EU. An EHC is an official document, signed by a veterinarian or authorised signatory, and is specific to the commodity being exported and the destination country. The EHC proves the consignment complies with the quality and health standards of the destination country. A consequence of a 'No-Deal' Brexit, could therefore be an increased demand for the processing of EHCs. How UK authorities would cope with such an increase, a process dependent on capacity, would have an impact on export. As EHCs would need to be signed by an Official Veterinarian or authorised signatory following inspection of the consignment[28], the availability of appropriately trained veterinarians or authorised signatories would again be critical to avoid disruption.

[25] Department for Environment, Food and Rural Affairs, 2018. Importing animals and animal products if there's no Brexit deal. https://www.gov.uk/government/publications/importing-animals-and-animal-products-if-theres-no-brexit-deal/importing-animals-and-animal-products-if-theres-no-brexit-deal

[26] House of Lords European Union Committee 2018. Brexit: plant and animal biosecurity. https://publications.parliament.uk/pa/ld201719/ldselect/ldeucom/191/191.pdf

[27] Department for Environment, Food and Rural Affairs, 2018. Importing animals and animal products if there's no Brexit deal. https://www.gov.uk/government/publications/importing-animals-and-animal-products-if-theres-no-brexit-deal/importing-animals-and-animal-products-if-theres-no-brexit-deal

[28] Department for Environment, Food and Rural Affairs, 2018. Importing animals and animal products if there's no Brexit deal. https://www.gov.uk/government/publications/importing-animals-and-animal-products-if-theres-no-brexit-deal/importing-animals-and-animal-products-if-theres-no-brexit-deal

7. Medicines and healthcare research and production

7.1. A 'No-Deal' Brexit scenario stands to have extensive impact on the UK biomedical sector, in particular as a result of asymmetry with respect to the EU as a future trading body, in the absence of bilateral regulatory and trading agreements. Given the time, monetary and human resources, and changes in legislation that will be required to relocate authorities and responsibility from the relevant EU bodies to the Medicines and Healthcare Products Regulatory Agency (MHRA), the UK may continue to accept certifications and product approval decisions obtained at EU level (at least for a temporary period), to avoid a supply crisis. This is despite the prerequisite that, should the UK receive third country status, we will automatically be out of the EU market from day 1 following formal exit of the UK from the EU. This situation will likely apply across the board, for example in relation to approval of new medicines, medical devices and products[29], orphan medicines (for rare diseases), and paediatric drug development[30]. In this scenario, UK biomedical research and development (R&D) industries may still be recognised in the EU through legal representation – though this option may not be within the resource capabilities of UK-based small and medium enterprises (SMEs).

7.2. Furthermore, in this scenario, despite the fact that UK SMEs will not be charged a fee for scientific advice by the MHRA, they will nonetheless cease to receive EU "financial and administrative assistance in accordance with Commission Regulation (EC) No 2049/2005 (the 'SME Regulation')"[31]. This will likely have a significant impact on the success of UK SMEs in competing with non-UK SMEs in the EU market, particularly where there may be reduced regulatory parity in relation to the development of new biomedical products. As a result, the UK may become a less attractive environment within which to base SMEs, by comparison with countries within the EU.

7.3. Even for multinational biomedical companies, the impact on the UK economy of a 'No-Deal' scenario is expected to be highly detrimental. There is concern that this scenario would act to push such companies to relocate resources away from the UK to other EU member states, so that manufacturing and batch test processes could continue to be carried out at competitive resource cost, in order to be accepted on the EU market – leading to severe implications for UK biomedical R&D contributions to the UK economy. Separate future MHRA approval processes may then be required for products for the UK market, leading to a duplication of efforts, and inefficient use of resources, across this important sector - unless an EU-UK agreement can be reached to safeguard regulatory parity and stability.

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[29] European Commission Directorate-General for internal market, industry, entrepreneurship and SMEs, (2018). Notice to stakeholders – Withdrawal of the United Kingdom and EU rules in the field of industrial products. https://ec.europa.eu/info/sites/info/files/file_import/industrial_products_en_1.pdf

[30] "If there's no deal, UK-based Notified Bodies *(a qualified third party required as part of the conformity assessment procedures for medical devices)* will no longer be recognised by the EU after the UK formally leaves the EU, meaning the devices they have certified will no longer be in conformity with the applicable EU Directive. As such these products will not be able to be placed on the EU market" as stated in point 2.3 of the Medicine and Healthcare products Regulatory Agency, (2018). Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal: https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

[31] European Commission Directorate-general for health and food safety and European Medicines Agency, (2018). Q&As related to the UK's withdrawal from the EU with regard to the medicinal products for human and veterinary use within the framework of the centralised procedure. Point 9, pages 4-5: https://www.ema.europa.eu/documents/other/questions-answers-related-united-kingdoms-withdrawal-european-union-regard-medicinal-products-human_en.pdf

7.4. Our members have previously commented that "Government commitment to convert existing EU marketing authorisations to those recognised by the UK on 29 March 2019 is welcome, but does not address the potential delays of getting new medicines to UK patients." [32] Despite the MHRA proposal to set up a CAP [33] conversion scheme to allow for EU-approved medicines to be accepted on the UK market, concern persists that a disorderly exit from the EU might affect UK patients' right to access novel treatments approved at an EU level. Our members have also raised the issue that in case of 'No-Deal', the "MHRA will lose access to the database of EU-approved products, so new generic applications would need to be based on reference products authorised in the UK. This could have large cost and productivity implications for the NHS[34]". The biomedical sector is also yet to see formal impact assessment of the proposed fees to be introduced by MHRA as part of their future regulatory role[35]. A further issue that has been raised by SMEs is with regard to the need for approval of new medicines, medical devices and products, orphan medicines and paediatric drugs in both jurisdictions (EU and UK): considering the cost of registration of a new medicinal product focus would invariably be on the larger market and hence this could lead to a lack of new medicines becoming available to UK patients in the short to medium term.

7.5. Additionally, members have raised concerns about the prospect of a sudden and serious impact on medicines supply because of border delays from customs checks. Such delays could also affect the quality of the cargo transported if it consists of time and temperature sensitive products[36]. Furthermore, there could be a projected increase in the cost of importing medicines, if the UK reverts to World Trade Organisation (WTO) tariffs; our members have previously commented that "it has been estimated that up to 1000 finished products and 700 ingredients are not currently included in the Pharmaceutical Tariff Elimination Agreement and would therefore be subject to tariffs when traded on WTO terms"[37].

7.6. Importantly, in relation to one of our key needs for collaboration, a 'No-Deal' scenario could jeopardise important relationships, such as with the European Medicines Agency (EMA), and participation in other EU networks for the sharing of data, resource and expertise, including "EudraVigilance, the system for tracking adverse reactions to medicinal products authorised, or in

[32] British Pharmacological Society, September 2018. Briefing from the British Pharmacological Society to inform the debate in the House of Commons Chamber on "Brexit, science and innovation" brought by Rt Hon Norman Lamb, Chair of the House of Commons Science and Technology Select Committee.

[33] *CAPs are medicines approved through the European Medicines Agency's centralised market authorisation route.*

[34] The King's Fund, 2015. How much has generic prescribing and dispensing saved the NHS? Available at: https://www.kingsfund.org.uk/blog/2015/07/how-much-has-generic-prescribing-and-dispensing-saved-nhs. As cited in the British Pharmacological Society, September 2018 Briefing from the British Pharmacological Society to inform the debate in the House of Commons Chamber on "Brexit, science and innovation".

[35] Medicine and Healthcare products Regulatory Agency, (2018). Further guidance note on the regulation of medicines, medical devices and clinical trials if there's no Brexit deal. See point 1.15: https://www.gov.uk/government/publications/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal/further-guidance-note-on-the-regulation-of-medicines-medical-devices-and-clinical-trials-if-theres-no-brexit-deal

[36] Written evidence from Merck (BRP0005): http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/business-energy-and-industrial-strategy-committee/leaving-the-eu-implications-for-the-pharmaceuticals-industry/written/73557.pdf

[37] Written evidence from the Association of the British Pharmaceutical Industry and the BioIndustry Association (BRP0001): http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/business-energy-and-industrial-strategy-committee/leaving-the-eu-implications-for-the-pharmaceuticals-industry/written/73078.html As cited in the British Pharmacological Society, September 2018 Briefing from the British Pharmacological Society to inform the debate in the House of Commons Chamber on "Brexit, science and innovation".

clinical trials, in the [European Economic Area] EEA"[38], which are priorities for the UK biomedical sector.

8. Plant breeding and research

8.1. Commercial plant breeding is a research-intensive process that produces new varieties of agricultural, horticultural and ornamental products. The sector creates substantial indirect benefits through improved yield and quality, and increased resilience to changing climatic conditions, which underpin not just the UK's food supply chain, but also provide benefit to people and practices in low and middle income countries.[39] Brexit will impose additional costs and burdens on the sector to test, protect and market new varieties in both the EU and the UK, should these become separate markets. While new opportunities may arise within this sector, as a result of Brexit and in relation to any subsequent community-agreed regulatory and legislative reform, a 'No-Deal' Brexit will create barriers to trade – for instance there will be an immediate ban on exports to the EU of UK produced seed and seed potatoes. Further, Defra and the Animal and Plant Health Agency are currently unlikely to have the necessary resources for policing and enforcement to combat a black market in seed imported from the EU and illegally marketed without having gone through the UK registration, undermining the legitimate seed trade. Barriers to trade, protection and marketing imposed by Brexit are likely to give UK farmers and growers a reduced choice of crop variety, and slower access to new varieties than competitors on the continent.

9. In conclusion

9.1. As always, ongoing consultation with all sectors of the community who contribute to and benefit from the biosciences will remain key to maintaining a welcoming and fertile environment for UK science and innovation, as partnerships change, the needs of society evolve, and new discoveries are made.

9.2. This should reiterate the key issues and identifies areas for further inquiry. The UK Government should be working to minimise impact on these sectors and ensure both the public and private space feel adequately prepared for.

We welcome the opportunity to comment on this important matter. The RSB is pleased for this response to be made publicly available.

For any queries, please contact the Science Policy Team at Royal Society of Biology, Charles Darwin House, 12 Roger Street, London, WC1N 2JU. Email: policy@rsb.org.uk

[38] British Pharmacological Society, September 2018. Briefing from the British Pharmacological Society to inform the debate in the House of Commons Chamber on "Brexit, science and innovation" brought by Rt Hon Norman Lamb, Chair of the House of Commons Science and Technology Select Committee.

[39] The UK Plant Breeding Sector and Innovation, 2016. Report for the Intellectual Property Office. HMSO, London Intellectual Property Office: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/552498/Plant-breeders.pdf

Appendix: 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
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 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 of Plant Breeders
British Society for Plant Pathology
British Society for Proteome Research
British Society for Research on Ageing
British Society of Animal Science
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
Gatsby Plant Science Education Programme (incl. Science and Plants for Schools)
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
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
Zoological Society of London

Supporting Organisational Members

Affinity Water
Association of the British Pharmaceutical Industry (ABPI)
AstraZeneca
BioIndustry Association
Biotechnology and Biological Sciences Research Council (BBSRC)
British Science Association
CamBioScience
Envigo
Ethical Medicines Industry Group
Fera
Institute of Physics
Ipsen
Medical Research Council (MRC)
MedImmune
Pfizer UK
Porton Biopharma
Procter & Gamble
Royal Society for Public Health
Syngenta
Understanding Animal Research
Wellcome Trust
Wessex Water
Wiley Blackwell