The Academy of Medical Sciences

Written response to Science and Technology Committee (Commons) Brexit Summit

February 2018

Summary

- Recent commitments on citizen's rights and continuing access to Horizon 2020 in joint report of negotiations on Orderly UK withdrawal are welcome and address two of the Academies short-term priorities.
- These commitments build on the ambition displayed in the Government's Future Partnership Paper.
- However, further detail is required on the arrangements that will exist during the transition period and the future research and innovation relationship.
- The Academy's priorities lie in three areas; ease of movement of researchers and research staff; continued access to collaborations, funds and infrastructure; and regulatory harmonisation.
- Science and research is highly international. In order to ensure the continued excellence of the UK's research base, the UK must establish a fair, transparent and efficient immigration system to enable continued ability to attract global talent.
- Participation in EU Framework Programmes supports UK research and researchers by allowing access to collaboration, networks and funding. The closest possible relationship with Framework Programmes will be mutually beneficial and would support international collaboration. The UK Government and the EU Commission's High Level Group on maximising the impact of EU Research & Innovation Programmes have both recognised this. Both the UK Government and EU Commission must now build on this consensus to establish how this can be achieved.
- Regulatory harmonisation will be the most favourable outcome in most instances in the life sciences. For example, the UK Government has recognised the need for continued close relationship with EU regulatory bodies, such as the European Medicines Agency, to protect UK patients' access to new medicines and protect public health and safety across Europe. However, details on how the nature of this relationship and how cooperation can be achieved are now required.
- The incoming Clinical Trials Regulation (CTR) lies outside the scope of the EU (Withdrawal) Bill. Harmonisation to this regulation should be prioritised by the UK Government and urgent clarity is required on how the UK will implement the regulation during the transition period.

Introduction

1. The Academy of Medical Sciences promotes advances in medical science, and works to ensure that these are translated into healthcare benefits for society. Our elected Fellowship includes the UK's foremost medical science experts drawn from academia and industry. This submission is informed by the expertise of our Fellowship and elements have been adapted from our previous work, including submissions to relevant Select Committee inquiries, joint work with the Wellcome Trust on EU Regulation of Research and Innovation and our submission to the Future Partnership Project.

2. The Academy views the key priorities for the future relationship with the EU to fall under three key themes, mobility of researchers; access to collaboration, funding and infrastructure; and regulatory harmonisation.

Ease of movement of research personnel

3. Science and research is an inherently international activity. A survey of the Fellows and grant holders of the UK national Academies revealed that 95% of respondents had been part of at least one international collaboration in the previous five years.[1] In 2015 almost 25% of medical research staff working in UK universities were non-UK EU nationals, with a further 14% from outside the EU.[2]
4. The ease of movement of researchers between countries is therefore an essential facilitator of research collaborations and research excellence. This encompasses researchers at all levels and career stages, from established world-leaders to early career researchers, PhD students as well as technicians and support staff.
5. In the future a permissive immigration system, which is fair, transparent and efficient must form part of a concerted approach to ensure that the UK remains, and is seen to remain, open to researchers from both within and outside the EU. This must allow for short term visits between collaborators, secondments and placements, as well as long-term or permanent relocation.
6. Wider environmental factors such as access to healthcare and education systems for researchers and their families form an important part of creating a welcoming, open and attractive environment.
7. The ability to attract and retain international talent will be required not only to support academic research, but also the highly international workforces of research-intensive private companies, for example 10% of Astra Zeneca's UK workforce are non-UK nationals.
8. Alongside an appropriate immigration system, funding which supports movement of researchers at different stages of their career can have transformative effects, particularly on early career researchers. These opportunities can expose individuals to different research cultures, practices and ideas and can drive the establishment of lifelong collaborations.
9. Existing EU programmes funded by the Marie Skłodowska-Curie actions (MCSA) such as Individual Fellowships and Innovative Training Networks represent some of the most productive examples of these schemes.[3] UK-based researchers have been highly successful in securing these awards in recent years, for example UK universities host the highest number of MCSA fellows.[4] Continued access to these schemes would be mutually beneficial for UK and EU researchers.

Government actions

10. The Academy of Medical Sciences welcomed the announcement in December that the rights of EU citizens currently in the UK and vice versa would be protected.

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[1] Opinion Leader (2017). The Role of international collaboratiojn and mobility in research https://acmedsci.ac.uk/file-download/96518966

[2] HESA data for 2015/16

[3] https://ec.europa.eu/research/mariecurieactions/about_en

[4] Technopolis (2017). The impact of collaboration: The value of UK medical research to EU science and health https://acmedsci.ac.uk/file-download/32381033

This provided much needed reassurance to EU nationals and their families currently living in the UK.[5,6]

11. The Government's Future Partnership Paper called for the UK to remain a hub for international talent. This, alongside investment of £100 million in the Rutherford Fund to attract highly skilled researchers to the UK and recent changes to the Tier One visa system for excellent talent are welcome signals of intent.[7,8]

Further requirements

12. The Academy awaits further details on the arrangement for EU nationals during the transition period, expected in a White Paper in early 2018.
13. An immigration system which allows UK institutions, businesses and the health service to continue to attract and retain the talent that they need from across the globe remains a key priority for the Academy.

Funding and infrastructure that is accessible to all partners on equal terms

14. UK HEIs received £725 million in research grant income from EU sources in 2014/15. This represented 12% of total HEI income from research grants and contracts (excluding QR).[9]
15. Clinical medicine (£120 million) and biosciences (£91 million) received the first and second highest volumes of funding from EU sources in 2014/15. Replacing these funds if the UK was no longer eligible to receive EU research funding would be challenging.[10]
16. European Research Council (ERC) grants now provide a significant proportion of the individual grants awarded to UK-based researchers and are firmly established as an important stream of funding for UK researchers.[11] ERC grants provide important support at different career stages and recipients of these grants are able to recover up to 100% salary, providing increased flexibility. Academy Fellows believe that these awards provide an important marker of international excellence that cannot be matched by national funding sources.
17. Additionally, international research collaborations are supported by mutually accessible funding streams. EU Framework Programme funding facilitates a range of activities which cannot be supported at a national level, these include funding for multinational consortia, such as through the Future and Emerging Technologies programmes or ERC Synergy Grants.[12,13]
18. Meanwhile, schemes such as the Innovative Medicines Initiative (IMI) link academia and industry. IMI provides access to expertise of over 7,000

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[5] https://acmedsci.ac.uk/more/news/brexit-negotiations-citizens-rights-and-financial-settlement
[6] Joint report from the negotiators of the EU and UK Government on progress during phase 1 of the negotiations under Article TEU on the UK's orderly withdrawal from the EU (2017) https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/665869/Joint_report_on_progress_during_phase_1_of_negotiations_under_Article_50_TEU_on_the_United_Kingdom_s_orderly_withdrawal_from_the_European_Union.pdf
[7] HM Government (2017) Collaboration on science and innovation: A future partnership paperhttps://www.gov.uk/government/uploads/system/uploads/attachment_data/file/642542/Science_and_innovation_paper.pdf
[8] https://royalsociety.org/about-us/competent-body/
[9] Technopolis (2017). The role of EU funding in UK research and innovation https://acmedsci.ac.uk/file-download/70343877
[10] *ibid*
[11] *ibid*
[12] http://ec.europa.eu/programmes/horizon2020/en/h2020-section/future-and-emerging-technologies
[13] https://erc.europa.eu/funding/synergy-grants

researchers across Europe and 55 public-private consortia, facilitating access to regulatory bodies, associations and patient organisations from around Europe. It would be challenging to replicate these examples on a national scale.

Government actions

19. The Government's pledge for financial contributions that will cover the continued participation in the remainder of Horizon 2020 is an important first step to providing clarity in the next two years. It is important to note that certain existing programmes, such as IMI, do extend beyond this date and it is not clear yet how they will be covered by this settlement.
20. The Future Partnership Paper indicated a willingness of the UK Government to explore models for engagement with future Framework Programmes, recognising the mutual benefit derived from collaborative working.
21. The Academy of Medical Sciences welcomed both of these commitments.[14,15]

Further requirements

EU Framework Programmes

22. The Academy believes that the UK should seek to attain the closest possible relationship with future EU Framework Programmes, as an essential component for securing successful future partnerships with EU27. A clear commitment from the UK that we wish to continue to participate in EU Framework Programmes must be accompanied by ongoing financial commitments.
23. The optimal scenario for future involvement of the UK in EU Framework Programmes would ensure the continued ability of UK-based researchers to participate on equal terms, including the ability to lead and shape specific programmes.
24. At present, the UK is an attractive research partner due to its excellent research base and research infrastructure. This is enhanced by the ability of UK researchers to fully participate in EU framework programmes. Erosion of this ability to participate would be detrimental to the attractiveness of the UK as a research partner.
25. Securing UK participation in future EU Framework Programmes will be subject to certain tensions, in particular the adherence to the principle of freedom of movement. It is promising that the recently published Lab-Fab-App report, called for future framework programmes to be "open to the world", by opening association to the best and participation to all. [16] A globally facing Framework Programme 9 should allow full and continued participation of the UK.
26. Whatever the outcome, there must be a seamless transition into the future partnership such that existing collaborations are not jeopardised or negatively affected by any period of uncertainty.

Links through non-Governmental Organisations

27. Active UK participation through non-governmental channels must also continue. This should include contact through specialist societies, Academies and European umbrella bodies, such as the Federation of European Academies of Medicine (FEAM), of which the AMS is a member.

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[14] https://acmedsci.ac.uk/more/news/brexit-negotiations-citizens-rights-and-financial-settlement
[15] https://acmedsci.ac.uk/more/news/dexeu-publishes-position-paper-on-science
[16] High Level Group on maximising the impact of EU Research & Innovation Programmes (2017) LAB – FAB – APP, Investing in the European future we want https://ec.europa.eu/research/evaluations/pdf/archive/other_reports_studies_and_documents/hlg_2017_report.pdf

28. FEAM is part of on the EU Commission's Scientific Advice Mechanism (SAM), through the network of European level Academies (SAPEA), representing an important and ongoing link to EU policy development.

European Investment Bank

29. It is worth noting that the Government's Future Partnership Paper does not consider the UK's future relationship with the European Investment Bank. The EIB makes loans at low rates to support its four priorities: Innovation and Skills, SMEs, Infrastructure, and Environment and Climate. Between 2007 and 2016, the EIB provided an estimated € 5.9 billion of loans to support research and innovation activities in the UK.[17] Of this €2.8 billion was provided to UK HEIs and knowledge transfer services and more than €2.5 billion to industry.[18]
30. Investment from the EIB (and the related European Investment Fund) in the UK has dropped dramatically since the EU referendum. In 2017 EIB's new contracts with the UK totalled €2.14 billion, compared to €6.96 billion and €7.77 billion in 2016 and 2015 respectively.[19,20,21] The EIB loan list shows no record of any loans provided to UK universities in 2017.[22]
31. The future ability of UK organisations to access EIB funds after EU exit is unclear.

Harmonised regulation

32. Regulatory alignment with existing EU regulations will, in many areas, be a favourable outcome for research and innovation, in particular in the life sciences.
33. The UK has employed a science-led, risk-proportionate approach to earn public confidence in the regulation of research and innovation. By employing this approach the UK has successfully promoted better research regulation in the UK and EU. Following EU exit, the UK's ability to influence future EU regulation will be diminished. However, value should be placed on harmonisation to existing and incoming regulation to ensure continuity, smooth collaborative working and minimise administrative burden. Regulatory divergence in the future, where deemed appropriate by the UK, would not be precluded by this broad approach.
34. At present clarity is urgently required for those operating under existing regulations, particularly within clinical research and the pharmaceutical sector.

Clinical trials

35. The UK coordinates the third highest number of pan-European clinical trials and the highest number for rare and childhood diseases.[23] This collaboration is supported by harmonised frameworks for conducting multinational trials.
36. As therapeutic interventions become increasingly targeted to individuals, research must be based on smaller patient cohorts making international collaboration essential. Thus, collaboration is not only important for patients with rare diseases, but for patients across Europe.

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[17] Technopolis (2017). The role of EU funding in UK research and innovation https://acmedsci.ac.uk/file-download/70343877
[18] *ibid*
[19] http://www.eib.org/projects/regions/european-union/united-kingdom/index.htm
[20] http://www.eib.org/attachments/general/reports/fr2016en.pdf
[21] https://www.gov.uk/government/news/new-figures-show-record-european-investment-bank-investment-in-uk-in-2015
[22] http://www.eib.org/projects/loan/list/index.htm?from=2013&region=&sector=5001&to=2018&country=GB
[23] Technopolis (2017). The impact of collaboration: The value of UK medical research to EU science and health https://acmedsci.ac.uk/file-download/32381033

37. A new EU Clinical Trials Regulation (CTR), originally due to apply from October 2018, has been delayed until the second half of 2019.[24,25] The UK was at the forefront of developing this new Regulation, which is widely considered to be a significant improvement on the existing Clinical Trials Directive (CTD). The delay to the application of this regulation has moved it outside the scope of the withdrawal bill.
38. Harmonisation to the incoming EU Clinical Trials Regulation and access to the portal that it will create should be prioritised by the UK. Clarity is urgently required on how the UK will achieve this during the transition period.

Use of animals in research

39. Shared regulations for the use of animals in research, as governed by the EU Directive 2010/63 and implemented in the UK through the Animals (Scientific Procedures) Act (ASPA) 1986 Amendment Regulations 2012 have provided a common framework for research using animals across the EU. This harmonisation has raised the required standards of welfare across the EU, facilitating pan-European collaboration and enhancing the attractiveness of the UK for commercial research involving animals.
40. The UK should maintain the existing standards to protect animal welfare, ensure public support and permit collaborative research. In the longer term, ASPA must keep up to date with emerging science, and the UK's relationship to EU regulation should be monitored to ensure it remains optimal.

Licencing of medicines, medical devices and in vitro diagnostics

41. The European Medicines Agency (EMA) is able to issue a single approval licencing a product across the EU. This approval from the EMA provides access to approximately 25% of the global pharmaceutical market. The UK alone represents approximately 3% of the global market. Nevertheless, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) provides substantial support to the EMA, acting as Scientific Advice Co-ordinator in at least 20% of EMA medicine approvals and conducting a substantial amount of work in inspection and enforcement standards on behalf of the EMA.[26]
42. Alongside the licensing of new drugs, the EMA also conducts post-marketing efficacy and pharmacovigilance studies across the EU. For example, the agency coordinates pharmacovigilance data from 28 member states through its EudraVigilance database. The UK has robust data collection which adds significant value to the data captured in this database. Recent trends to accelerate approval regimes, have seen innovative medicines enter the market at earlier stages in their development. These innovative licensing schemes further necessitate the need for evaluation of risk-benefit profiles on the basis of much smaller clinical trial data. Therefore, the rigorous collection, monitoring, and evaluation of post-licensing safety and efficacy data becomes increasingly important.[27] This is best conducted at an international level and is currently facilitated by the EMA.

[24] http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000629.jsp
[25] http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2017/10/news_detail_002824.jsp&mid=WC0b01ac058004d5c1
[26] Technopolis (2017). The impact of collaboration: The value of UK medical research to EU science and health https://acmedsci.ac.uk/file-download/32381033
[27] EL Jackson, P Feldschreiber, and A Breckenridge (2017), Regulatory Consequences of "Brexit" for the Development of Medicinal Products. Clinical Pharmacology and therapeutics, Vol. 102, no. 2

43. Continued collaboration between the MHRA and EMA would be mutually beneficial.

Medical Devices and *In vitro* diagnostics

44. New EU legislation to regulate medical devices and In vitro diagnostics (IVD) will come into force in 2020 and 2022 respectively. This legislation represents an improvement on existing regulation, providing a more robust regulatory framework for devices, including more emphasis on evidence generation around their effectiveness. There is strong support in the sector for maintenance of regulatory alignment for devices between the UK and EU. A survey by the Association of British Healthcare Industries found that only 3% of members who responded supported regulatory divergence with the EU.[28]
45. In addition, continuity in the CE marking system will ensure that products developed in the UK continue to be recognised in the EU and around the globe, and that products developed in the EU can continue to be recognised in the UK. This is important to maintain NHS patient access to innovative devices, and facilitate access for UK device companies to the EU and broader market. The system of Notified Bodies granting CE marks should therefore be maintained and mutual recognition of the existing UK Notified Bodies should be explored.

Government actions

46. The Government's future partnership paper highlighted the starting point of "close regulatory alignment" and the need for the agreement on science and innovation to "provide a framework for future cooperation". In addition the paper emphasised the UK's commitment to a continuing close working relationship with the European Medicines Agency (EMA), which was first set out in the joint letter to the Financial Times from the Secretaries of State for Health and Business Energy and Industrial Strategy.
47. The Parliamentary Under-Secretary (Department of Health), Steve Brine MP, recently confirmed that the Government continues to work "towards implementation of the new Clinical Trials Regulation, whose application date will be set by the European Commission".[29]
48. In a speech delivered in September 2017, Lord O'Shaughnessy, Parliamentary Under Secretary of State for Health, confirmed that the incoming Devices and IVD Regulations will be covered by the Withdrawal Bill and committed to working towards "strong, effective technical collaboration" between regulatory agencies and notified bodies "that accelerates scientific advancement and ultimately benefits patient wellbeing".[30]

Further requirements

49. Recent announcements have provided welcome clarity that the jurisdiction of the European Courts of Justice will continue during the implementation period. This is absolutely necessary to provide time to adapt to future arrangements. However, the transition period will only be useful if the future requirements are established early on in the negotiations.

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[28] http://www.abhi.org.uk/membership/members-area/updates/2017/july/impact-of-brexit-2017-member-survey-results/

[29] Ministerial response to written Parliamentary question – 105651 (October 2017) http://www.parliament.uk/business/publications/written-questions-answers-statements/written-question/Commons/2017-10-06/105651/

[30] https://www.gov.uk/government/speeches/lord-oshaughnessy-on-medical-technologies-and-brexit

50. For example, in the pharmaceuticals sector uncertainty around the mutual recognition of qualified persons in batch testing of medicines is driving organisations to invest in facilities outside the UK. This is necessary to ensure that medicines manufactured in the UK can continue to be sold within the EU in the event that mutual recognition of qualified persons is not achieved. This would not be a desirable outcome, but indicates that pharmaceutical companies are being forced to make decisions in the absence of clarity on future relationship to ensure secure supply chains in the long-term.
51. Additionally, regulatory harmonisation will depend not only on enshrining of EU standards in UK law through the EU (withdrawal) bill, but the ongoing relationship with the relevant EU bodies and agencies, such as the EMA, the European Chemicals Agency and ultimately the European Courts of Justice. A pragmatic solution must be found enabling, for example, the MHRA to operate as a sovereign regulator, whilst maintaining an ongoing relationship and equivalence with the EMA. The recent concessions over citizen's rights and the ability to make technical referrals to the ECJ may offer a potential model.

Conclusion

52. The Government's Future Partnership Paper and the UK/EU agreement for an "Orderly UK withdrawal" have helped to provide short term reassurances and to clarify the Government's ambition to maintain collaboration with EU research and to retain access to EU research funding.
53. The Academy agrees that an ambitious agreement, such as that proposed by the UK Government and endorsed by the LAB- FAB- APP, would be mutually beneficial for EU and UK medical research, ultimately delivering the best outcomes for patients and citizens at home and abroad.
54. Further detail and clarity is required as soon as possible to provide the certainties the sector needs.

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