ROYAL PHARMACEUTICAL SOCIETY England

House of Commons Science and Technology Committee
Brexit science and innovation Summit

About the Royal Pharmaceutical Society

1. The Royal Pharmaceutical Society (RPS) is the professional body for pharmacists in Great Britain. We are the only body that represents all pharmacy sectors in Great Britain. The RPS leads and supports the development of the pharmacy profession including the advancement of science, practice, education and knowledge in pharmacy.

Response

2. An update from the Medicines and Healthcare products Regulatory Agency (MHRA) in January 2018 noted that the UK is "fully committed to continuing the close working relationship with its European partners, in the interests of public health and safety". We welcome the aim to ensure patients "continue to be able to access the best and most innovative medicines and be assured that their safety is protected through the strongest regulatory framework and sharing of data".[1] At the same time, ahead of a final deal being agreed, there remains significant uncertainty across the healthcare and life sciences sector as to the potential impact of Brexit on a number of key areas. These are detailed below.

Workforce

3. There is uncertainty over the long-term workforce implications of any potential Brexit outcome and the impact on organisations to recruit and retain talent, whether that is in healthcare services, academia or research and industry. Smarter use of the UK healthcare workforce will be crucial, making the most of the skills and talent of all the health professions and encouraging new ways of working and joined-up services to reduce pressures on the system and help keep people out of hospital.

Research

4. Research funding is a key issue, such as risks to the loss of Horizon 2020 funding, and there are concerns about how withdrawal from the EU will affect UK researchers' scientific partnerships. Many academic researchers are currently both leading and collaborating in EU consortia that are funded by competitive EU grants and it is unclear whether there would be arrangements for this to continue, or if not how any future funding gaps will be offset. Questions remain as to whether the UK would pay to become an associate member of EU research programmes and how this would affect its ability to influence priorities. However this is not just about funding but about the added value of intellectual sharing of ideas.

5. It is essential that Brexit is negotiated so that the UK pharmaceutical and biotechnology industries have access to European markets, and any lost research income is replaced.

6. Over recent years the rapidly increasing cost and complexity of research has meant that collaboration with colleagues both within and beyond the EU has become more important. Consideration needs to be given to aspects such as researcher mobility, the purchase, operation and maintenance of joint equipment, as well as the dissemination and exploitation of the research. Brexit negotiations must avoid adding unnecessary extra layers of complexity that put

[1] MHRA update to pharmaceutical companies on exit preparations, January 2018 www.gov.uk/government/news/mhra-update-to-pharmaceutical-companies-on-exit-preparations

an extra burden on the researchers and thereby reducing value for money. At the same time, working closely with other countries offers wider opportunities to learn from each other about innovative service models in health care.

7. Current scientists and researchers, together with those EU nationals who come to work in the UK prior to departure from the EU, should have the right to remain for the duration of their existing contracts or courses under the same conditions as before. This must include scientists and researchers who have permanent positions with open-ended contracts. Similarly, current undergraduate and postgraduate students, together with those EU nationals who have come to the UK prior to any formal departure from the EU, should continue to be charged fees equivalent to UK students.

Workforce, education and training

8. The UK pharmaceutical science and life sciences sector is reliant on a highly-skilled and qualified workforce that is multidisciplinary in composition and flexible across sectors and geographies. As well as enabling UK citizens to work in the EU and beyond, the UK should remain welcoming and attractive to the world's best talent and their families.

9. The RPS report 'New Medicines, Better Medicines, Better Use of Medicines' recommended encouraging investment in scientific education and training to ensure a skilled and adaptive pharmaceutical science workforce, which would support the UK's continued position as a leader in life sciences.[2]

10. The National Audit Office notes that in 2015 the UK spent 1.68% of UK GDP on research and development.[3] UK spending on R&D needs to be closer to the OECD average of 2.4% and this should help fund an increase in the number of PhDs in pharmaceutical science supported by the Industrial Strategy Fund. It will also be important to fund post-doctoral posts and more senior fellowships. This includes applied health scientists and clinical academics. Although some support is available from the National Institute of Health Research and Medical Research Council, this is not sufficient to support the strong scientific base that the UK needs.

11. The UK should seek to ensure mutual recognition of education qualifications within the EU, a key issue in supporting a sustainable workforce, not only in the life sciences sector but across the NHS.

12. The UK should work to ensure mutual recognition of Qualified Persons, who are required to certify batches of medicinal products prior to use in a clinical trial (human medicines products only) or prior to release for sale and placing on the market (human and veterinary medicinal products). We would welcome an assurance that existing rules relating to Qualified Persons, currently defined in Directive 2001/83/EC, will be translated into UK law.

Innovation and access to treatment

13. New EU Clinical Trials Regulations are set to come into force by the end of 2018. These regulations are meant to harmonise procedures for assessing clinical trials applications, as well as enhancing collaboration between ethics committees, streamlining safety-reporting

[2] Royal Pharmaceutical Society, *New Medicines, Better Medicines, Better Use of Medicines*, 2014 www.rpharms.com/resources/reports/new-medicines-guide

[3] National Audit Office, *Cross-government funding of research and development*, 2017 www.nao.org.uk/wp-content/uploads/2017/11/Cross-government-funding-of-research-and-development-Summary.pdf

procedures and increasing transparency surrounding the outcome of clinical trials. These regulations will create a centralised gateway for clinical trial applications. The Government should provide reassurance that UK patients will not be left out of this new system, otherwise it risks leaving EU patients ahead in accessing the latest innovative clinical research and reducing access to sources of research income.

14. It is imperative for the Life Sciences sector that the UK remains actively involved with and contributing to the various regulatory agencies, such as the European Medicines Agency (EMA). The Medicines and Healthcare products Regulatory Agency (MHRA) currently plays a major role as rapporteur for registration filings as it is a much respected and valued competent authority.

15. The impact of Brexit on medicines licensing through loss of access of centralised processes, currently performed by the EMA, needs to be fully understood. Duplicate arrangements may need to be introduced leading to inefficiency and inconstancies in access to medicines. It is likely to involve the pharma and biotech industries in additional work and cost, increasing the cost of the drug development pipeline which might ultimately be passed onto the NHS and may result in new and innovative medicines not being licensed in the UK, to the detriment of patients in the UK.

16. As well as issues relating to the regulation of medicines and the future of the UK's relationship with the European Medicines Agency, any future Brexit deal should take into consideration future arrangements relating to intellectual property and patents. The Government confirmed in November 2016 that the UK will proceed with preparations to ratify the Unified Patent Court Agreement, but is yet to confirm how it will work with the court once the UK leaves the EU and whether pharmaceutical companies would need to seek patent protection in the UK separately from the new pan-EU patent system.

17. A supportive tax system would foster continued patient access to innovation developed in the UK, such as through Patent Box-type mechanisms or R&D tax credits.

A Life Sciences Minister

18. The Government should appoint a dedicated Life Sciences Minister, with UK-wide responsibilities, to fulfil a strategic role in engaging with the sector, provide reassurance during the negotiation period and help shape the Government's approach to Brexit negotiations.

The Royal Pharmaceutical Society

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