ROYAL PHARMACEUTICAL SOCIETY England

House of Commons Health Select Committee
Brexit – medicines, medical devices and substances of human origin

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.

Responses to questions

> *Q.1 What are the key considerations that arise for companies, healthcare services and regulatory bodies in the UK as a result of the UK's withdrawal from the EU? Focussing on patients and the public, what needs to be done to ensure that any adverse impact is minimised or eliminated, and that opportunities to enhance services are maximised?*

2. 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.

3. 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 part of EU consortia that are funded by competitive EU grants and it is unclear 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.

4. We welcomed the Government setting out its aim "to ensure that patients in the UK and across the EU continue to be able to access the best and most innovative medicines". It has noted that the "UK and the EU start from a position of close regulatory alignment" and should seek to minimise any additional regulatory burdens resulting from Brexit.

5. The future of the European Medicines Agency (EMA) will have an impact not only on its employees in the UK, but also on the medicines regulation. There is uncertainty as to whether the UK will remain as a Reference Member State and the effect on patient access to medicines.

6. The sector would welcome clarity from the Government on how any Brexit deal will affect the implementation of the Falsified Medicines Directive (FMD), which sets out to protect residents within the EU from counterfeit medicines and includes a series of stipulations covering almost every aspect of the supply of medicines; from the manufacture of active pharmaceutical ingredients and excipients, through distribution and up to the point of dispensing.

> *Q.2 Following the UK's withdrawal from the EU, what alternative arrangements for the regulation of medicines, medical devices, medical products and substances of human origin could be introduced? What are the respective opportunities, risks and trade-offs involved?*

7. The UK should seek to retain its position as an EMA Reference Member State. Risks of the UK's withdrawal from the EU include delays in in approval and access to medicines. There are also questions as to the impact on sharing of pharmacovigilance data, such as the UK's future relationship with EudraVigilance - the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised in the European Economic Area.

   Q.3 How much time is needed to facilitate a smooth transition to new arrangements? Is it possible, or desirable, to move directly to new arrangements post-29 March 2019, or are transitional arrangements needed?

8. The potential outcome from any Brexit negotiation is uncertain. The length or type of any transition would depend on how closely the UK might seek to retain current arrangements.

   Q.4 How will withdrawal from the European Union affect the UK's ability to influence international standards in life sciences?

9. 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.

10. The UK should seek to ensure mutual recognition of education qualifications within the EU. The UK should also 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.

    Q.5 What arrangements are needed to ensure the safe, effective and timely supply of medical radioisotopes over the short, medium and long-term?

11. Radiopharmacists are involved with the procurement, preparation, quality control and supply of radiopharmaceuticals. UK hospitals and radiopharmacies will need continued access to European suppliers. A number of factors will influence the supply of medical radioisotopes. Safe and rapid transport from continental cyclotrons and reactors could be affected by any potential delays at border controls. Another factor is regulatory compliance with the EMA, International Atomic Energy Agency and Euratom. The Medicines and Healthcare products Regulatory Agency (MHRA) will require sufficient support to liaise with EU regulators, including around good manufacturing practice.

    Q.6 What are the implications for medical research and development, including for the timely patient access to new medicines, technologies and other relevant medical innovations developed within or outside the U.K? How can any adverse consequences be avoided or mitigated and any potential opportunities be enhanced?

12. 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.

13. 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 an extra burden on the researchers and thereby reducing value for money.

14. 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.

15. 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.

16. 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.[1]

17. UK investment in research and development needs to be closer to the OECD average and this should 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. 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.

18. 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 procedures and increasing transparency surrounding the outcome of clinical trials. These regulations will create a centralised gateway for clinical trial applications. However, Brexit means that UK patients will be left out of this new system, leaving EU patients ahead in accessing the latest innovative clinical research. The likely impact on the UK of not being involved in these new regulations needs to be carefully assessed.

19. There are concerns over potential divergence from the EU medicines regulatory system. 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 MHRA currently plays a major role as rapporteur for registration filings as it is a much respected and valued competent authority.

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[1] *New Medicines, Better Medicines, Better Use of Medicines*, RPS 2014
www.rpharms.com/resources/reports/new-medicines-guide

20. It would be beneficial if the UK could remain an EMA Reference Member State and the impact of Brexit on medicines licensing through loss of access of centralised processes, currently performed by the EMA, needs to be fully understood.

21. If duplicate arrangements were introduced this may lead 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.

22. In the Health Select Committee session on 10 October 2017 the Chief Executive of NHS England highlighted what he described as an "extremely challenging" funding environment. Against that backdrop, as part of any Brexit negotiation the Government should seek to minimise any additional import duties on medicinal products from the EU, which might increase costs for NHS organisations and adversely affect patient access to treatment.

23. The Government should appoint a dedicated Life Sciences Minister, with UK-wide responsibilities, to fulfil a strategic role in engaging with the sector and shaping the Government's approach to Brexit negotiations.

The Royal Pharmaceutical Society

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