Written evidence from the Royal Pharmaceutical Society

House of Commons Health Select Committee
Impact of a no deal Brexit on health and social care

1. The Royal Pharmaceutical Society’s submission to the Committee’s inquiry on Brexit – medicines, medical devices and substances of human origin previously set out a number of issues relating to the potential impact of a ‘no deal’ Brexit on health and social care.¹

2. While this submission does not seek to replicate earlier evidence in full, as attention on a possible ‘no deal’ Brexit has intensified in recent months, there remain concerns in several of the policy areas highlighted previously.

3. On 4 October the Medicines and Healthcare products Regulatory Agency (MHRA) also opened a consultation on EU Exit no-deal contingency legislation for the regulation of medicines and medical devices.

4. A ‘no deal’ Brexit will impact on the ability of 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, including pharmacists, and encouraging new ways of working and joined-up services to reduce pressures on the system and help keep people out of hospital.

5. Research funding is a key issue and ‘no deal’ will significantly affect UK researchers’ scientific partnerships if it does not comply with EU rules in order to retain associate member status. It is already widely agreed across the research community that if the UK defaults to ‘third country’ status this will reduce funding available to research consortia. There is evidence that some UK researchers are already being side-lined amid continued uncertainty over the long-term implications of Brexit.

6. We agree with the Government that patients in the UK and across the EU should “continue to be able to access the best and most innovative medicines”. We welcomed the Government’s intention for the UK to continue participating in agencies for highly-regulated sectors, including for medicines, supported by arrangements covering all relevant compliance activity to reduce additional regulatory burden.

7. Without a negotiated deal, risks of the UK’s withdrawal from the EU include delays in patient access to medicines. This is a concern shared across the healthcare sector, including members of the Brexit Health Alliance.² This concern is recognised by the Government’s Medicines Supply Contingency Planning Programme announced in August, which covers products that are prescription-only medicines and pharmacy-only medicines, but does not include general sales list (GSL) products.³

8. We have welcomed steps by the Government to provide reassurance over continued patient access to medicines, including steps to “ensure the UK has an additional six weeks’ supply of medicines”. Questions remains as to how this will work in practice, including what quantity “six weeks’ supply” means for certain medicines, how long these measures would remain in place, and whether demand might be affected by seasonal variation.

9. Short-term shortages of medicines due to supply chain issues or increased demand are not uncommon and pharmacists frequently help manage these in their everyday practice, ensuring patients are able to receive appropriate treatment. This role will become increasingly important in the event of ‘no deal’ Brexit.

10. The Secretary of State for Health and Social Care has warned against stockpiling of medicines in the NHS and stated that there was no need for clinicians to write longer prescriptions. At the same time, health professionals may face difficult conversations with patients concerned about access to their medicines and so the Government should continue to provide further reassurance and clarity to the public over the steps being taken to protect medicines supply.

11. The Government should consider what guidance might be provided for health professionals to help alleviate potential shortages in medicines supply, such as substituting generic for branded medicines, or substituting a product which is therapeutically equivalent.

12. There are significant concerns that the lack of a withdrawal agreement will lead to cutting off UK’s access to European Medicines Verification Organisation (EMVO) database for implementation of the Falsified Medicines Directive (FMD). FMD 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.

13. The MHRA has stated that in the event of no deal being agreed it would ‘expect the UK would not have access to the EU central data hub, and therefore stakeholders would be unable to upload, verify and decommission the unique identifier on packs of medicines in the UK’. Its preferred approach would see the UK accept packs containing FMD safety features in the UK, provided that they are in line with other UK packaging requirements, adding that, ‘in the interests of public safety, we will evaluate the options around a future national falsified medicines framework’. If the UK does not adopt the same standards as the rest of the EU it risks becoming a target market for counterfeit medicines.

14. 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 authorised in the European Economic Area.

15. We agree with the MHRA that it is in the interest of patients and the life sciences industry for the UK and EU to continue cooperation in the field of clinical trials, and for continued sharing of data. The recent suspension of a clinical trial of dutogluptin has underlined the potential impact of uncertainty around Brexit the importance of ensuring the UK retains its position as a leader in medicines research.

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16. New EU Clinical Trials 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 on the outcome of clinical trials. These regulations will create a centralised gateway for clinical trial applications. A ‘no deal’ Brexit risks leaving UK patients out of this new system, putting them behind other EU patients in accessing the latest innovative clinical research.

17. The MHRA has noted that in the event of a ‘no deal’ Brexit ‘the extra costs of complying with a new UK regulator could be passed onto the purchaser through higher prices of medicines’. As the NHS develops a new Long-Term Plan it will be vital to maximise the proportion of additional funding which goes towards improving patient care. Additional regulatory burden should be avoided to ensure the UK remains an attractive market for new and innovative medicines.

18. Given the potentially far-reaching implications for the health service, research, and pharmaceutical sciences, in the event of a ‘no deal’ Brexit, the Government should plan for bilateral agreements on key areas, including our future relationship with bodies such as the European Medicines Agency to ensure patients continue to be able to access the best and most innovative medicines.

About the Royal Pharmaceutical Society

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.

The Royal Pharmaceutical Society

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