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Impact of leaving the EU on health and social care in Scotland

The Royal Pharmaceutical Society (RPS) is the professional body representing individual members of the pharmacy profession from across all settings and sectors. As such, we welcome the opportunity to respond to the Scottish Parliament Health & Sport Committee's call for evidence and have outlined some of the key areas that may be affected by the UK exiting the EU.

The full picture of the implications of Brexit on both health and social care will not be known for quite some time. The outcome of the current negotiations will be the deciding factor. The uncertainty around this and the realisation of the scale of regulation and legislation, which will have to be considered, has led to wide concern both on the possible long term consequences and on the potential for disruption during a transition period.

In reviewing the many reports and analyses of the situation to date it is apparent that, whilst workforce and staffing might have quite immediate effects, there are many more subtle aspects which will have far reaching and damaging implications for our health and social care systems. This will, in turn, affect the future of patients unless a successful negotiation to ensure close working relationships with the EU is achieved.

We have highlighted some of the major issues which have so far been discussed across the pharmacy profession and in pharmaceutical sectors, but the list below is not exhaustive.

Patient access to new and emerging treatments

The exit of the European Medicines Authority (EMA) from the UK to Amsterdam has been a setback for the UK.

New EU Clinical Trials Regulations are set to come into force by the end of 2018. These regulations are intended 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. The likely impact on the UK of not being involved in these new regulations needs to be carefully assessed.

Although in theory the UK will still be available for clinical trials and have a robust regulatory process through the Medicines & Healthcare products Regulatory Agency (MHRA), the change in market size as a standalone nation will change manufacturers' perspective on where to market and launch new medicines. The UK is currently less than 3% of the world market (with reports that this figure is decreasing). In comparison the total figure for the EU is 27%.

If the relationship between the UK and EU becomes 'more distant', it is highly likely that the UK will lose access to the single marketing authorisation offered by the EMA. This means that in order for a pharmaceutical company to get a new medicine on the UK market they will have to undergo an extra regulatory hurdle (i.e. a separate approval process by the MHRA). The cost involved in this process could be considerable thereby making the UK a less attractive market for pharmaceutical and biotech companies. The anticipated result of a 'more distant relationship' being negotiated is that new medicines will be launched first in the EU with introduction in the UK following once manufacturers apply for approval in the UK, thus delaying UK patients' access to innovative new medicines.

The UK should therefore seek to retain its position as an EMA Reference Member State.

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.

There are some very specialist areas which could be affected and will impact on patient care in areas such as radiotherapy treatment for cancer patients and more general diagnostic testing.

Radiopharmacists are involved with the procurement, preparation, quality control and supply of radiopharmaceuticals. UK hospitals and radiopharmacies rely on imported products and will need continued access to European suppliers. A number of factors will influence the supply of medical radioisotopes. Safe and rapid transport could be affected by any potential delays at border controls. Another factor is the requirement for regulatory compliance with the EMA and so the MHRA will require sufficient support to liaise with EU regulators, including around good manufacturing practice.

We welcome the UK 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".

Medicines Supply Chain Issues

We note and support the UK Government announcement of an independent analysis of the implications of Brexit for the medicines supply chain.

The medicines supply chain is complex. There are many areas from regulation and licencing, through to all stages of production and packaging and then supply which could be affected. Medicines shortages are already a global problem and present daily challenges for Scottish pharmacists. Pharmacists and their teams already spend considerable time sourcing medicines for their patients both in primary and secondary care and, whilst to date they have managed to source alternatives for their patients, further disruption could result in patient harm if alternatives cannot be sourced.

The NHS also benefits from being able to buy from such a large market. The depth of supplies available helps avoid the risk of shortages. The 'parallel trade' where medicines are bought from countries where they are cheaper than the UK saves pharmacists, who are contracted with the NHS, money; this helps to pay for their services with less government funding and acts as a competitive pressure on the prices of the pharmaceutical industry. The direct benefits of this in the UK have been estimated at £100 million.[i]

Counterfeit and Falsified Medicines

We understand that the implementation of the Falsified Medicines Directive (FMD), is still planned to go ahead in February 2019 regardless of the UK's exit from the EU. This directive sets out to protect residents within the EU from counterfeit medicines and includes a series of requirements 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.

There are however concerns over the approaching deadline for implementation. Further clarity is still required on many aspects of the implementation. Close alignment with Europe is imperative in order secure the patency of the protection being established across Europe by the Directive.

Medical Research

Currently both academic and industrial research benefits from EU membership. 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. The strength of these collaborations is evidenced by the fact that 60% of the international co-authors on UK research publications are from the EU [Universities UK (2016)].[ii]

Therefore there is a requirement for continued close collaboration with the EU in order to sustain our current level of innovation.

The EU research budget invests heavily in UK healthcare and life sciences research; it benefits from the active engagement of UK universities and industrial laboratories taking part in research – both collaboratively with other EU entities and individually. Many academic researchers are currently part of an EU consortia that is funded by competitive EU grants and it is unclear how any future funding gaps will be offset.

According to a House of Lords report the UK pays out £5.4bn to support EU research activities but gets back an estimated £8.8bn in grants to UK universities. Indeed the UK is estimated to get over 15% of the Horizon 2020 funding (second only to Germany). However, there is already evidence of an increasing reluctance amongst EU collaborators for the UK to lead or even be involved in EU projects, resulting in reduced research and development funds being made available to UK academic and research institutions.

This reluctance of EU colleagues to work with UK partners is a deeply concerning trend as it is acknowledged that the UK's science research output is considerably enhanced by the involvement of European and International collaborations. Indeed it is estimated that over 60% of the UK's science research output is in the form of European and International collaborations, while research that involves European/International collaborations has 50% more impact than solely UK research and research papers[iii].

Workforce

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. We must make the most of the skills and talent of all health professions, encouraging new ways of working with joined-up services to reduce pressures on the system and help keep people out of hospital.

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. In fact only 62% of the current UK academic staff are native to the UK, while 23% are from the EU, the remaining 15% are from wider afield [Universities UK (2015)]. In addition, it has been reported that pharmaceutical companies already struggle to recruit for highly skilled roles in the UK due to low numbers of good quality candidates. This could lead to firms increasingly seeking expertise and skills abroad[iv].

The UK should therefore 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.

Nuffield trust has estimated[v] that by 2025 the UK could face a shortfall of social care workers by as much as 70,000. This will impact on our care home services as well as other vulnerable groups such as sheltered housing and other supported accommodation. A shortfall in social care provision will further increase demand for health services.

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[i] Nuffield Trust (2017), 'Getting a Brexit deal that works for the NHS': https://www.nuffieldtrust.org.uk/files/2017-05/getting-brexit-deal-for-nhs-web-final.pdf, accessed 25 January 2018.

[ii] Royal Pharmaceutical Society (2016), written evidence on Leaving the EU: Implications and Opportunities for Science and Research.

[iii] The Royal Society (2016), 'UK research and the European Union The role of the EU in international research collaboration and researcher mobility ': https://royalsociety.org/~/media/policy/projects/eu-uk-funding/phase-2/EU-role-in-international-research-collaboration-and-researcher-mobility.pdf, accessed 25 January 2018.

[iv] ABPI (2015), 'Bridging the skills gap in the biopharmaceutical industry Maintaining the UK's leading position in life sciences': https://www.abpi.org.uk/media/1365/skills_gap_industry.pdf, accessed 25 January 2018.

[v] Nuffield Trust (2017), 'Getting a Brexit deal that works for the NHS': https://www.nuffieldtrust.org.uk/files/2017-05/getting-brexit-deal-for-nhs-web-final.pdf, accessed 25 January 2018.