



Law Society
of Scotland

Written Evidence

EU HOME AFFAIRS SUB-COMMITTEE

BREXIT: RECIPROCAL HEALTHCARE

November 2017



Introduction

The Law Society of Scotland is the professional body for over 11,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's solicitor profession.

We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective solicitor profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom Governments, Parliaments, wider stakeholders and our membership.

The Society's Health and Medical Law Sub-committee welcomes the opportunity to consider and respond to the EU Home Affairs Sub Committee Call for Written Evidence on Brexit and reciprocal healthcare.

General comments

In September 2017 we submitted an analysis paper to the Scottish Parliament's Health and Sport Committee. The submitted paper¹ provides a brief reflection on the impact that leaving the European Union may have on healthcare and public health in the United Kingdom with particular focus on Scotland. We are aware that some decisions have recently been taken, notably the relocation of the European Medicines Agency.

As the current call for evidence relates directly to the policy area of health, it is appropriate that we include a copy of the submitted paper, which we hope will be of assistance to the EU Home Affairs Sub Committee in their consideration of the potential impacts on the healthcare sector as a result of the UK leaving the European Union.

We are also actively engaging with the UK and Scottish Parliament in their consideration of the European Union Withdrawal Bill 2017 - 2019²

¹ The UK withdrawal from the EU and the potential impact on health related matters – Law Society of Scotland Analysis Paper

² <https://www.lawscot.org.uk/research-and-policy/influencing-the-law-and-policy/our-input-to-parliamentary-bills/bills-201718/european-union-withdrawal-bill-2017-19/>

Specific comments

Current regulatory regime

- **What is your assessment of the current arrangements for reciprocal healthcare? To what extent is it effective and for whom?**
- **Assuming that the UK will be treated as a ‘third country’ once the UK is no longer a member of the EU, what will be the default position as a matter of law for healthcare coverage for UK citizens in the EU, and vice versa, if no agreement is in place on day one of Brexit?**

Response:

1. Cross-border healthcare is one of the most direct ways that citizens of the UK and across the EU will be affected if existing collaborative and reciprocal arrangements cease to have effect. There are around 1.2 million UK migrants living in other EU countries, compared with around three million EU migrants living in the UK³ and there are concerns that the referendum result may mean that UK pensioners currently living elsewhere in the EU return, which may increase pressures on health and social care services. The Nuffield Trust suggests that the cost per head in the UK for the treatment for those aged over 65, is £4,950 per year.

‘As the NHS has never been very effective in reclaiming the fees owed to it by overseas visitors to the UK, the UK may find itself substantially worse off financially when new arrangements for funding cross-national use of health services are put in place.’⁴

2. There are a number of routes for citizens resident in the UK to obtain medical treatment in another EU state. For example:
 - a) The EHIC is designed to cater for the unplanned health needs of tourists. This is for emergencies and covers only treatment provided by the state as opposed to private treatment ;
 - b) The “S2 route” in which, after prior authorisation has been obtained by the patient, the UK pays the other state directly to provide particular treatment. This also is restricted to state health care. The patient has to pay any contribution to the costs that a local citizen in the other state would have had to pay. In some countries this could amount to 25% of costs;

³ Migration Watch UK (2016) *The British in Europe and Vice Versa*. Available from: <https://www.migrationwatchuk.org/briefing-paper/354> [Accessed 19 June 2017]

⁴ Majeed, A (2017) ‘What impact will Brexit have on public health and health services in the United Kingdom?’ *Better Health For All*. Available from: <https://betterhealthforall.org/2017/03/06/what-impact-will-brexit-have-on-public-health-and-health-services-in-the-united-kingdom/> [Accessed 30 May 2017]

- c) The rights arising from Directive 2012/52/EU⁵ to treatment in another state, including private treatment, although the patient must pay upfront and apply to be reimbursed. In this case prior authorisation from the UK health authority is also required in some circumstances.
3. For UK nationals who are permanently resident in another EU state, the possibilities are:
 - a) For those in receipt of an “exportable benefit” (most commonly retirement pension), they are likely to qualify for state health care in the country of residence, paid for by the UK;
 - b) Other UK nationals need to apply to the state in which they are resident and will be entitled to state-provided health care from that state on the same basis as nationals of that country.

Clearly, all of these routes to cross-border health care are vulnerable and their future implementation uncertain.

4. ECJ case law had gradually established that EU citizens of one country had the right to travel to other EU states to receive medical treatment and that the patient should not have to pay. The circumstances surrounding reimbursement of medical costs incurred overseas remained unclear. Some answers were provided by the ECJ in the 2006 case of *Yvonne Watts v Bedford Primary Care Trust*⁶. A British NHS patient had gone to France for a hip replacement because of the long waiting list at her local health authority. At home she was refused reimbursement of her costs. The ECJ considered that the Treaty on freedom to provide services included this particular set of circumstances and held that a national waiting list could not be used to justify withholding rights to cross-border treatment. It also settled the question of whether cross-border rights applied only between insurance-based systems as some had previously maintained. The court held that taxpayer-funded systems such as the NHS were also subject to these rights.
5. Following this case the Directive 2011/24/EU⁷ of the European Parliament and of the Council on patients’ rights in cross-border health care was issued and implemented in Scotland by The National Health Service (Cross-border Health Care) (Scotland) Regulations 2013. These were amended in 2015 to facilitate recognition of medical prescriptions between member states.⁸ The National Health Service (Cross-border Health Care) (Scotland) Regulations 2013 provide for

⁵ Available from: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0052> [Accessed 19 June 2017]

⁶ *Yvonne Watts v Bedford Primary Care Trust* C-372/04

⁷ <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:sp0002>

⁸ The National Health Service (Cross-border Health Care) (Scotland) Directions 2015 also instructed health boards on various standards and procedures to be adopted, for example in “undue delay” and telemedicine cases.

reimbursement of costs of health care in another EEA country to which the patient has specifically travelled for the purpose of receiving that treatment. The entitlement is to private or state health care. Reimbursement is up to the level of the costs which would otherwise have been borne by the home country. Importantly, reimbursement is only for treatment which is the same or equivalent to treatment to which the patient would have been entitled at home. This rules out some treatments, for example, proton beam therapy, available in Europe for a wider range of conditions than in the UK.

6. Prior authorisation from the home health board is required if an overnight stay in hospital or the use of highly specialised equipment is involved or in cases of particularly high risk. The health board can refuse authorisation if the treatment can be provided at home within a “medically justifiable” time limit, opening up the issue to a spectrum of medical opinion as to the appropriate waiting time for treatment in any individual case and potentially diluting the patient’s ability to avoid the waiting list at home.
7. The perception is that this route to treatment is less widely used than the others. Although the regulations contain a requirement to set up a national contact point giving information on access to health care in the EU, this route may be too little known as yet. The requirement to pay upfront and apply to be reimbursed is probably also a considerable disincentive for some patients.
8. Apart from conferring the above rights to cross-border health care, Directive 2012/52/EU supported other initiatives, albeit in a less prescriptive fashion. It was somewhat visionary in its ambitions for coherent European health care and medical and scientific co-operation. It promoted European Reference Networks and centres of excellence to enhance co-operation to develop a better capacity for the diagnosis and treatment of rare diseases and the use of telemedicine.
9. At the time of writing and following the most recent negotiations, it has been agreed⁹ that the existing reciprocal arrangements will continue in relation to the European Health Insurance Card (EHIC). This will apply to EU citizens in the UK and UK citizens currently residing in an EU state whether they are studying, working or retired. This will be the case if you are resident in an EU country on the day that the UK leaves the EU. However, for UK or EU citizens who wish to travel

⁹ European Commission Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU and the UK. Available from: file:///C:/Documents%20and%20Settings/abri/My%20Documents/Downloads/joint_table_citizens_rights_-_third_round.pdf [Accessed 5 September 2017] TF50 (2017) 16 - Commission to EU27 at p. 11 ‘Healthcare –personal scope’.

and avail themselves of these arrangements, the position is currently less clear. The EU wishes to see further progress made on separation agreements before future arrangements can be negotiated.

10. If the routes as discussed above are no longer available, then citizens have to rely more heavily on private insurance to provide for treatment abroad. There are clearly equality issues with an insurance based system. For example, the cost of insurance for the elderly and those with pre-existing health problems is likely to be more expensive than average.
11. Many Britons who have retired to EU states currently benefit from the “S1 scheme” under which the UK pays for the healthcare of expatriate pensioners, many of whom live in France and Spain. This is a reciprocal scheme, but the number of retired Britons living in EU states is higher than retired EU nationals living here.
12. If this scheme were to be discontinued, these pensioners would be obliged to obtain private health insurance or potentially have to contribute to local social security schemes. They are eligible for free healthcare in the UK, but the return of potentially large numbers of patients for treatment could be an additional strain on the NHS resources.
13. We note that in the Association of British Insurers’ evidence to the EU Home Affairs Committee on 25th October¹⁰ estimated medical costs associated with the treatment of British citizens under the EHIC at the moment is £156 million. They indicate that total claims for travel insurers currently are worth £369 million and additional claims under EHIC are worth £156 million and while Association of British Insurers & the Association of Medical Insurers and Intermediaries did not envisage 50% increase in premiums they did concede that increases could be in the region of 20% - this would impact disproportionately on those on lower incomes, assuming that they can secure cover, and again would impact on significant numbers of the EU 27 citizens in the UK who have S1 status social care, pensions.
14. We note that ABTA’s research¹¹ suggested that nearly one in four travellers holidaying abroad travel without health insurance (an increase from one in five) in 2011 and nearly half (48%) of 25-24 year olds travel without insurance and nearly 1/3rd already consider insurance too expensive with

¹⁰ <http://data.parliament.uk/writtenevidence/committeeevidence.svc/evidencedocument/eu-home-affairs-subcommittee/brexit-reciprocal-healthcare/oral/72965.html>

¹¹ <https://abta.com/about-us/press/numbers-travelling-abroad-uninsured-on-the-rise>

17% of travellers assuming that EHIC will provide equivalent cover to insurance (although it doesn't provide cost of repatriation to the UK).

15. One significant issue is that EHIC is not charged based on any pre-existing condition or disability while according to Scope¹², the disability charity, some 26% of disabled adults already feel they are charged more for insurance, or simply denied it, on account of their conditions, Scope have called for transparency to be brought to the process, and more support to be offered to disabled people calling on the Financial Conduct Authority (or the UK Government) to enforce change.

EEA Nationals

16. The status of EEA nationals requiring healthcare in the UK will become the same as that of non-EEA nationals. As a matter of UK immigration law, persons coming to the UK who apply for a visa to remain in the UK for more than six months have to pay an immigration health surcharge.¹³ Those granted indefinite leave to remain are entitled to free NHS healthcare.
17. For *visitors* to the UK access to healthcare is determined by whether a person is “ordinarily resident” in the UK. There are separate, although similar, Scottish provisions.¹⁴
18. Broadly, the regulations provide that overseas visitors have to pay for NHS medical treatment with the cost being collected by the NHS provider. Accident and emergency treatment is free and some treatment is exempt from charges, for example the treatment of infectious diseases and family planning.
19. In addition, there are categories of persons, such as asylum seekers and refugees who are exempt from these charges.
20. The UK has reciprocal arrangements with a list of countries outside the EEA and residents of those countries may be exempt from charges depending on the terms of the bilateral arrangement. Over time, similar agreements could be negotiated with EU/EEA states.

Government's proposals for UK citizens already living and working in the EU

- **What is your assessment of the Government's current proposals to the EU regarding**

¹² [https://www.scope.org.uk/getattachment/Get-Involved/Campaigns/Campaigns-content/2016-WYSIWYG/Working-for-all-text/Improving-access-to-insurance-for-disabled-people-\(August-2017\).pdf.aspx](https://www.scope.org.uk/getattachment/Get-Involved/Campaigns/Campaigns-content/2016-WYSIWYG/Working-for-all-text/Improving-access-to-insurance-for-disabled-people-(August-2017).pdf.aspx)

¹³ The Immigration (Health Charges) Order 2015 amended in 2017.

¹⁴ NHS (Charges to Overseas Visitors) (Scotland) Regulations 1989 amended in 1992 and 1994. There is also non-legally binding advice on this in the Chief Executive Letter (CEL) 9 (2010).

reciprocal healthcare arrangements post-Brexit? What changes, if any, would you recommend?

Response:

21. Current challenges regarding staffing of the NHS tend to be interrelated and centre around shortage of staff, working conditions and low morale. Within the UK as a whole, the NHS faces difficulties in recruiting and retaining permanent staff. The UK has a ratio of 278 doctors per 100,000 of the population compared to an EU average of 347 per 100,000.¹⁵ Similar problems can be seen in the social care sector not only in relation to vacancy rates but also high turnover.¹⁶
22. The EU's legislative underpinning of freedom of movement and mutual recognition of professional qualifications within the EU provides for health and social care professionals from other EU countries to work within the NHS. Following Brexit, this will no longer apply. This may deter those who are considering moving to the UK as well as having, as yet unknown, implications for those already working in the UK.
23. The GMC records show that about 11% of doctors registered in the UK gained their professional qualifications from another EEA country.¹⁷ 5.8% of doctors in Scotland are recorded as qualified in another EU country, but this does not take account of EU citizens who trained in Scotland so the real number is likely to be higher.¹⁸
24. Section 6.3 of the UK Government's White Paper on Brexit and future partnership with the EU aims to 'secure the status of EU nationals currently in the UK'¹⁹. To this end, a policy paper was published as a UK Government paper on 26 June 2017 which set out proposals for safeguarding the position of EU citizens living in the UK and UK nationals living in the EU.²⁰ The policy paper

¹⁵ Cylus, J et al (2015) United Kingdom Health System Review. Health Systems in transition. 17 5 1-126.

¹⁶ The King's Fund(2016) *Five big issues for health and social care after the Brexit vote* Available from:

<https://www.kingsfund.org.uk/publications/articles/brexit-and-nhs> [Accessed June 5 2017]

¹⁷ Letter to the Editor(2017) Brexit and the NHS: Challenges, uncertainties and opportunities *Health Policy* 121 477-480, at p 477 Available from: [http://www.healthpolicyjrn.com/article/S0168-8510\(17\)30062-3/pdf](http://www.healthpolicyjrn.com/article/S0168-8510(17)30062-3/pdf) [Accessed June 5 2017]

¹⁸ Robson K, (2016) , 'The National Health Service in Scotland' Scottish Parliament SPiCe 'The National Health Service in Scotland' at p.3. Available from: http://www.parliament.scot/ResearchBriefingsAndFactsheets/S5/SB_16-100_The_National_Health_Service_in_Scotland.pdf [Accessed 30 May 2017]

¹⁹ Dept. For Exiting the European Union (2017) The United Kingdom's exit from and new partnership with the European Union. Available from: <https://www.gov.uk/government/publications/the-united-kingdoms-exit-from-and-new-partnership-with-the-european-union-white-paper/the-united-kingdoms-exit-from-and-new-partnership-with-the-european-union--2> [Accessed June 5 2017]

²⁰ HM Government. (2017) The United Kingdom's Exit from the European Union Safeguarding the Position of EU Citizens Living in the UK and UK Nationals Living in the EU. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/621847/60093_Cm9464_NSS_SDR_Print.pdf [Accessed July 12 2017]

proposes that EU citizens living in the UK will qualify for 'settled status'²¹ if they have been continually resident in the UK for five years.

25. It also promises to protect access to UK pensions, economic and other rights and these will be addressed in other sections of this paper.²² At time of writing, calls for clarity have been made, for example, whether students, who will be allowed to stay in the country to finish courses, will be able to remain after the completion of their studies in order to work.²³

26. Another point to note is that the WTD has been the focus of some contention. It regulates average working hours and health and safety requirements through rest periods and annual leave. Possibly one of the highest profile areas has been in relation to junior doctors in training, traditionally characterized by long hours of 'on call'. Doctors in training were brought fully within the scope of the working time directive in 2009 meaning that the maximum amount of time worked cannot exceed 48 hours per working week. The British Medical Association has expressed their satisfaction with the WTD, but others, for example such as those working in acute care, have expressed concerns that it is unnecessarily inflexible and restrictive.^{24 25}

27. It should be noted that the WTD is essentially a health and safety mechanism and it is for this reason employers are, for instance, required to keep records of hours worked. In Scotland the regulations are incorporated into the *Agenda for Change*²⁶ and reflected in Scottish Health Board protocols. Negotiating departure from the EU may impact upon NHS employment contracts or require significant changes to the framework agreement.

²¹ This is defined in the UK Government paper as 'indefinite leave to remain pursuant to the Immigration Act 1971'. Summary Proposals Principle 6.

²² Ibid- Principle 7.

²³ Boffey, D. (2017)

Citizens' rights: EU chief Brexit negotiator calls for more clarity from UK The Guardian. Available from:

<https://www.theguardian.com/politics/2017/jun/26/citizens-rights-eu-chief-brexit-negotiator-calls-for-more-ambition-from-uk> [Accessed July 20 2017]

²⁴ Letter to the Editor(2017) Brexit and the NHS: Challenges, uncertainties and opportunities *Health Policy* 121 477-480, at p 478 Available from: [http://www.healthpolicyjrn.com/article/S0168-8510\(17\)30062-3/pdf](http://www.healthpolicyjrn.com/article/S0168-8510(17)30062-3/pdf) [Accessed June 5 2017]

²⁵ One possible way to resolve this is by way of the 'opt out' mechanism contained in the WTD. This mechanism operates whereby an individual, on a voluntary basis, elects to sign a waiver with their employer agreeing that they are happy to work additional hours. It is important to note that it is not possible to opt out of the rest requirements, so doctors would still need to ensure they take the necessary breaks, and their employer would still need to monitor the hours they work. Opt Out is not unique to the UK and other EU countries permit a broad use of Opt Out, for example, Bulgaria, Cyprus, Estonia & Malta. Other members permit the Opt Out but only in relation to certain occupations, including health care sectors. For example, Belgium, Czech Republic, France, Germany, Hungary, Latvia, the Netherlands, Poland, Slovakia, Slovenia and Spain.

²⁶ *Agenda for Change*, implemented on 01 October 2004, represents a major reform of pay and other terms and conditions for all NHS staff with the exception of Medical and Dental Staff and some Senior Managers. It is the first significant reform of NHS pay since the Health Service was established in 1948. See in summary- <http://www.msg.scot.nhs.uk/pay/agenda-for-change/afc-in-summary> [Accessed July 13 2017]

Affected groups

- **Which groups (e.g. people with disabilities, long-term conditions, children, etc.) and/or categories (e.g. residents, students, non-residents, etc.) will be most affected by any changes to existing reciprocal healthcare arrangements?**
- **What should be the priorities for these groups in terms of the negotiations and future UK law?**

Response: Please refer to our paper within the appendix.

Implications for the UK health and social care sectors

- **What impact would ending reciprocal healthcare arrangements with the EU have on the UK health and social care sector?**
- **What would be the financial, staffing, and other implications for the UK health sector if reciprocal healthcare arrangements were to end?**

Response: Please refer to our paper within the appendix.

APPENDIX

Analysis Paper

The UK withdrawal from the EU and the potential impact on health related matters

September 2017

Introduction

The Law Society of Scotland (the Society) is the professional body for over 11,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's legal profession.

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This paper, written by the Health and Medical Law Sub-committee of the Law Society of Scotland, provides a brief reflection on the impact that leaving the European Union may have on healthcare and public health in the United Kingdom with particular focus on Scotland. Since June 2016, there has been a significant amount of discussion on this but, given that the negotiations to agree what a post Brexit landscape may look like are far from conclusion, views can only be conjecture. What can be seen is the emergence of recurring themes and issues further grouped within them. It is these that will be the subject of what is considered here.

We note that the UK Parliament's EU Home Affairs Sub-Committee has recently launched a new inquiry into reciprocal healthcare after Brexit and we intend to respond to the call for evidence in due course²⁷.

²⁷ <http://www.parliament.uk/business/committees/committees-a-z/lords-select/eu-home-affairs-subcommittee/news-parliament-2017/brexit-reciprocal-health-inquiry/>

Key points

28. The UK's withdrawal from the European Union will affect many aspects of the provision of health and social care.
29. In April 2017, the UK Parliament's Select Committee on Health published its report on the potential impact of the UK withdrawal.²⁸ It suggested that *'[T]he Department of Health produce a comprehensive list of those issues that will require contingency planning.'*²⁹
30. We suggest that the Scottish Parliament should undertake a similar such an inquiry from a Scottish health and social care perspective.
31. We believe that Scotland has differing requirements from the rest of the UK and this may be partly due to the structure of NHS Scotland. More will be said on this throughout this paper and will include discussion on Scotland's reliance on a work force from overseas, the impact of EU regulations, cross border collaboration for medical research and the distinctive ethos which underpins its provision of healthcare.
32. There are now signs that 'alliances' of shared interests are being formed across many areas including health. For example, the Brexit Health Alliance.³⁰
33. We recommend continuous monitoring to help ensure that UK negotiators appreciate a clear understanding of the Scottish arrangements regarding health and the implications of withdrawal.
34. Many such initiatives and alliances of shared interests will unsurprisingly take a broad UK perspective and it is suggested that Scotland should be viewed as distinctive. We recommend that the relevant stakeholders in Scotland should promote a clear understanding and promotion of how its organisations are currently structured, their existing strengths and future priorities.

²⁸ Brexit and health and social care—people & process. (April 2017) Available from: <https://publications.parliament.uk/pa/cm201617/cmselect/cmhealth/640/64002.htm> [Accessed Sept 2 2017]

²⁹ Brexit and health and social care—people & process. (April 2017) para 6. Available from: <https://publications.parliament.uk/pa/cm201617/cmselect/cmhealth/640/64002.htm> [Accessed Sept 2 2017]

³⁰ http://www.amrc.org.uk/sites/default/files/doc_lib/Brexit%20Health%20Alliance%20Asks.pdf

35. The regulation of health by the EU can be understood within a thematic approach to policy making. We recommend that scrutiny to be given to ascertain overall costs and benefits of existing EU regulation.
36. We recommend consideration be given as to how individual states, both within and outwith the EU, have implemented or incorporated EU health regulation with a view to developing workable post-Brexit options for the UK.
37. Medical licensing remains a major concern and the UK has to make a decision on how it will licence medicines in the UK once it leaves the European Medicines Agency. We recommend an evaluation of the existing contributions and alignments from major organisations such as the Medicines and Healthcare products Regulatory Agency (MHRA) as well as a review of the role of other organisations which have, to date, not played a part.
38. Health care coverage is a highly visible priority for UK citizens. Whilst it has been agreed that the existing reciprocal arrangements will continue in relation to the European Health Insurance Card (EHIC) for those resident in EU states prior to the Brexit date, for UK or EU citizens who wish to travel and avail themselves of this arrangement post Brexit, the position is currently less clear. We recommend that negotiations are given priority in this area and reciprocal and mutually beneficial arrangements for health care coverage and maintaining cross border healthcare are progressed.
39. Health research is another area which succeeds on the basis of strong networks producing excellence and innovation within the health related disciplines. These networks are already fracturing. We recommend that the UK and EU seek ways to preserve the major contribution that the UK currently makes to research within the EU. We believe that given the willingness of those who work in this area, current negotiations may provide an opportunity to foster new relationships and stronger collaboration in the future.

Background and Context

40. The NHS in the UK is comprised of NHS England, Scotland, Wales and Northern Ireland. It is the 5th largest employer in the world employing some 1.7 million people.³¹ It is argued that Scotland has

³¹ The NHS Choices information,(2017) *About the National Health Service* Available from: <http://www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx> [Accessed 5 June 2017]

differing requirements from the rest of the UK and this may be partly due to the structure of NHS Scotland.

41. Scotland has a population of approx 5.295 million while the United Kingdom as a whole totals 65.54 million. The total budget in Scotland for health and wellbeing in 2016/17 is £13.04 billion. This accounts for 35.1% of the total Scottish Government budget.³² This compares to a £107 billion budget for NHS England³³ yet prior to June 2016, hospitals in England declared a deficit of £2.5 billion.³⁴
42. Additional yet similar concerns exist across the UK and can be grouped around rising clinical demand and patient expectation, a growing and ageing population, reductions in social care funding, deterioration of key target performance and an increase in the costs of medicines and health technologies.³⁵
43. Despite those similarities, it is important to recognise that NHS Scotland, NHS England and NHS Wales are distinctive organisations. This is not just about budget and economies of scale but business ethos and structure too.
44. 'NHS Scotland has undergone significant changes over the last two decades.'³⁶ Initially these changes centred around the dismantling of the internal markets but in recent years, NHS Scotland focus has been on quality of care,³⁷ patient experience which would include for example, shorter waiting times, and more recently, the integration of health and social care.^{38,39} *'In part because of its relatively small size and close-knit profession...Scotland has preserved the service's original*

³² Robson K, (2016) , 'The National Health Service in Scotland' Scottish Parliament SPICe 'The National Health Service in Scotland' at p.3. Available from: http://www.parliament.scot/ResearchBriefingsAndFactsheets/S5/SB_16-100_The_National_Health_Service_in_Scotland.pdf [Accessed 30 May 2017]

³³ NHS England (2016) *Our 2016/2017 Business Plan* Available from: <https://www.england.nhs.uk/wp-content/uploads/2016/03/bus-plan-16.pdf> [Accessed 23 May 2017]

³⁴ Letter to the Editor(2017) Brexit and the NHS: Challenges, uncertainties and opportunities *Health Policy* 121 477-480, at p 477 Available from: [http://www.healthpolicyiml.com/article/S0168-8510\(17\)30062-3/pdf](http://www.healthpolicyiml.com/article/S0168-8510(17)30062-3/pdf) [Accessed June 5 2017]

³⁵ Letter to the Editor(2017) Brexit and the NHS: Challenges, uncertainties and opportunities *Health Policy* 121 477-480, at p 477 Available from: [http://www.healthpolicyiml.com/article/S0168-8510\(17\)30062-3/pdf](http://www.healthpolicyiml.com/article/S0168-8510(17)30062-3/pdf) [Accessed June 5 2017]

³⁶ Robson K, (2016) , 'The National Health Service in Scotland' Scottish Parliament SPICe 'The National Health Service in Scotland' at p.3. Available from: http://www.parliament.scot/ResearchBriefingsAndFactsheets/S5/SB_16-100_The_National_Health_Service_in_Scotland.pdf [Accessed 30 May 2017]

³⁷ BBC Scotland news online. 'UK health services could 'learn lessons' from Scottish NHS. Available from: <http://www.bbc.co.uk/news/uk-scotland-40494488> [Accessed August 21 2017]

³⁸ Since the 1st April 2016, territorial health boards and local authorities have been required to integrate certain health and social care services. This has resulted in the creation of 31 integration authorities, usually called Integrated Joint Boards (IJBs). For further discussion on this point, please see Robson at pp12-13

³⁹ Dayan M and Edwards N (2017), Learning from Scotland's NHS. Research report. Nuffield Trust. Available from: <https://www.nuffieldtrust.org.uk/files/2017-07/learning-from-scotland-s-nhs-final.pdf> [Accessed August 21 2017]

*ethos by stressing collaboration, shared expertise and mutual aid.*⁴⁰ Meanwhile, the English model is characterised a little more by elements of competition and choice.⁴¹

45. More tangible distinctions exist too, for example, Scotland, follows the Welsh approach where medical prescriptions are free for all patients.⁴² Other Government policy initiatives from 2007 include; The 2010 publication of the NHS Quality Strategy for Scotland⁴³, The publication of the 2020 Vision in 2012,⁴⁴ and a commitment to protect the health budget⁴⁵ and Realising Realistic Medicine in 2016.⁴⁶

European Union Regulation

46. Within the European Union, health policy tends to fall within 4 themes:

1. Mobility - e.g. healthcare professionals and EU citizens cross border access to healthcare;
2. Free trade - e.g. authorisation and regulation of medicines;
3. Research and new technology;
4. Management and promotion of public health.

The emphasis here can lean towards policy rather than politics and it is therefore useful to focus on individual states to understand how they implement or interpret these themes.⁴⁷

47. The health service in the UK is currently subject to a number of EU regulations governing procurement, regulation of medicines and devices as well as facilitating common professional standards, medical education and working practices between European Economic Area (EEA) countries. The law which will provide for the UK's exit from the EU has now been tabled before Westminster parliament. It proposes, through the provisions of the European Union (Withdrawal) Bill (the bill),⁴⁸ that it will 'freeze frame' the body of existing EU law, as it exists on Brexit day, into domestic law. After which, on the basis that the supremacy of EU law will have ended, the UK

⁴⁰ Statement attributed to Catherine Calderwood, Chief Medical Officer for Scotland and Peter Bennie of BMA Scotland in The Guardian, 'How healthcare differs across the UK' Available from: <https://www.theguardian.com/politics/2016/feb/09/how-healthcare-differs-across-the-uk> [Accessed 30 May 2017]

⁴¹ Feeley, D. (2013) Derek Feeley: what are the differences between the English and Scottish health systems? Available from: <https://www.kingsfund.org.uk/time-to-think-differently/audio-video/derek-feeley-what-are-differences-between-english-and-scottish-health-systems> [Accessed 30 May 2017]

⁴² ... at a cost of £1.2bn a year – including £10m a year on free paracetamol. in The Guardian, 'How healthcare differs across the UK' Available from: <https://www.theguardian.com/politics/2016/feb/09/how-healthcare-differs-across-the-uk> [Accessed 30 May 2017]

⁴³ <http://www.gov.scot/Resource/Doc/311667/0098354.pdf>

⁴⁴ <http://www.gov.scot/Resource/0042/00423188.pdf>

⁴⁵ The publication of Better Health, Better Care set out the SNP Government's vision of creating a 'mutual NHS'.

⁴⁶ <http://www.hi-netgrampian.org/wp-content/uploads/2017/03/Realistic-Medicine-Report-Feb-2017.pdf>

⁴⁷ For a fuller discussion on these themes, see Chapter 3 of Laurie G.T, Harmon S, H E, Porter G. (2016) Mason and McCall Smith's *Law and Medical Ethics* 10th edition. Oxford: Oxford University Press.

⁴⁸ <http://services.parliament.uk/bills/2017-19/europeanunionwithdrawal.html>

Parliament, and the devolved legislatures and assemblies, will then decide which elements of that law to keep, amend or repeal.⁴⁹

48. The bill also provides for what are being referred to as 'Henry VIII powers', where the UK Government, without substantive reference to parliament, will be able to decide which regulations will remain as they are, or whether they will be amended or repealed. This may yet need to be clarified further since;

The wide scope of this power becomes clear when looking at the explanatory notes published alongside the Bill. These talk about powers to implement a "no deal" scenario if the EU and UK do not come to terms on Brexit, including powers to "remove" the rights of EU citizens resident in the UK.⁵⁰

49. The proposals also state that ties to the European Court of Justice (CJEU) will be severed since new UK law will be passed which will define citizens' rights after Brexit. This means that it will have no jurisdiction on any cases not currently before it on the day that the UK leaves the EU.

50. This decision continues to raise concerns. First, the EU position is that the CJEU should continue to have jurisdiction over cases that originate in UK courts before UK's departure date. *'[T]his would apply even where the facts of the case occurred before withdrawal'⁵¹*

51. A further concern is that this may lead to a lack of reciprocity in terms of human rights for Britons living in EU states against those EU citizens living in the UK.⁵² The EU has proposed to continue to protect social, employment and residency rights which UK citizens living in another EU state but some of those are not reciprocated within the current proposals, particularly in terms of the right to bring family members to the UK. Included in the bill is a statement from the Secretary of State for

⁴⁹ The EUROPEAN UNION (WITHDRAWAL) BILL EXPLANATORY NOTES, paragraph 22. Available from: <https://www.publications.parliament.uk/pa/bills/cbill/2017-2019/0005/en/18005en.pdf> [Accessed July 14th 2017]

⁵⁰ Peers, S (2017) Law expert: where the Brexit battles over the repeal bill will be fought in parliament. The Conversation. Available from: https://theconversation.com/law-expert-where-the-brexit-battles-over-the-repeal-bill-will-be-fought-in-parliament-80980?utm_medium=email&utm_campaign=Latest%20from%20The%20Conversation%20for%20July%2017%202017%20-%2078606262&utm_content=Latest%20from%20The%20Conversation%20for%20July%2017%202017%20-%2078606262+CID_8161da3cb3ddb33c36abcd913c0ca94&utm_source=campaign_monitor_uk&utm_term=what%20the%20Bill%20would%20do%20in%20its%20current%20form [Accessed July 17 2017]

⁵¹ HM Government, (2017) Ongoing Union judicial and administrative proceedings POSITION PAPER (July 13 2017) Available from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/627910/FINAL_OFF_SEN_Position_paper_HMG_Ongoing_Union_judicial_and_administrative_proceedings_Position_Papers_FINAL_120717_2_1_.pdf [Accessed July 14 2017]

⁵² O'Carroll, L (2017) Britons' rights in Europe 'must not surpass rights of EU citizens in UK' The Guardian. Available from: https://www.theguardian.com/politics/2017/jul/13/brexit-britons-rights-in-europe-must-not-surpass-rights-of-eu-citizens-in-uk?CMP=Share_AndroidApp_Outlook [Accessed 14 July 2017]

Exiting the European Union⁵³ that he believes that the provisions of the bill are compatible with the European Convention on Human Rights. It is worthwhile noting that Norway and other EEA states are bound by the ECJ's rules.

52. Despite the fact that some regard the presence of the ECJ as a direct challenge to notions of UK sovereignty, the role of the ECJ is fettered by the fact that it can only rule where it has the competence to do so and when it is requested.⁵⁴ Whatever the position turns out to be within the UK, it is highly probable that the British citizens living in another EU state will remain subject to any ruling of the ECJ.

Reserved or devolved?

53. Matters pertaining to health have been largely devolved to the Scottish Parliament so that it could enter into reciprocal arrangements.⁵⁵ *Leaving the EU means, amongst other issues, the UK setting up a range of new or beefed-up agencies and regulatory structures (from drugs to environment to nuclear materials and more), returning powers to the devolved administrations, developing its own separate trade policy, and beginning to differentiate UK law from EU law*⁵⁶

54. However, there are some important areas which are still reserved to Westminster.⁵⁷ These include:

- Xenotransplantation, i.e. the use of non-human organs for transplantation;
- Embryology, surrogacy and genetics;
- Medicines, medical supplies and poisons - although decisions on the funding of medicines are devolved. See below for a consideration of the role of the Scottish Medicines Consortium;
- The regulation of the health professions that were regulated prior to devolution⁵⁸ (the regulation of newly regulated professions is devolved). For example, the professional regulation of doctors is reserved to Westminster, but the General Medical Council operates within the legal and legislative structures of the different jurisdictions within the UK. Their

⁵³ Rt Hon Davis Davis MP

⁵⁴ Wesemann, A. (2017) EU citizens proposal: a lawyer examines in detail. *The Conversation*. June 27 2017. Available from : <https://theconversation.com/eu-citizens-proposal-a-lawyer-examines-the-detail-80111> [Accessed 13 July 2017]

⁵⁵ As per the provisions of the Scotland Act 1998

⁵⁶ Hughes, K (2017) Scotland: What Strategy as Brexit Talks Get Under Way? Scottish Centre on European Relations Available from: <https://www.scer.scot/database/ident-2191> [Accessed July 20 2017]

⁵⁷ An excellent overview is provided by Kathleen Robson in the Scottish Parliament's SPICe Briefing in December 2016, 'The National Health Service in Scotland' Available from: http://www.parliament.scot/ResearchBriefingsAndFactsheets/S5/SB_16-100_The_National_Health_Service_in_Scotland.pdf [Accessed 30 May 2017]

⁵⁸ the regulation of newly regulated professions is devolved.

guidance for doctors reflects the laws of Scotland, and this is reflected in their guidance and policies;⁵⁹

- Health and safety (including the working hours of healthcare staff through the provisions of the Working Time Directive (WTD)).

55. The Medical Act 1983 contains a number of provisions for the registration of UK and EEA applicants, the definition of basic medical training and definitions of specialist medical training that are grounded in EU law. As part of the process of disentangling UK and EU law, we understand that the UK Department of Health (DoH) will need to review the Act and decide where it wants to abrogate, retain or modify EU law. We expect the DOH to do this in consultation with the UK Governments, the devolved authorities and the GMC and the other professional regulators.

56. The WTD has been the focus of some contention. It regulates average working hours and health and safety requirements through rest periods and annual leave. Possibly one of the highest profile areas has been in relation to junior doctors in training, traditionally characterized by long hours of 'on call'. Doctors in training were brought fully within the scope of the working time directive in 2009 meaning that they should have a maximum amount of time worked cannot exceeds 48 hours per working week. The British Medical Association have expressed their satisfaction with the WTD, but others, for example such as those working in acute care, have expressed concerns that it is unnecessarily inflexible and restrictive.^{60 61}

57. It should be noted that the WTD is essentially a health and safety mechanism and it is for this reason employers are for instance required to keep records of hours worked. In Scotland the regulations are incorporated into the *Agenda for Change*⁶² and reflected in Scottish Health Board protocols. Negotiating departure from the EU may impact upon NHS employment contracts or require significant changes to the framework agreement.

⁵⁹ General Medical Council. European and External Relations Committee The EU referendum and its implications for Scotland Written submission from General Medical Council. Available from: http://www.parliament.scot/S5_European/General%20Documents/General_Medical_Council.pdf. [Accessed July 21 2017]

⁶⁰ Letter to the Editor(2017) Brexit and the NHS: Challenges, uncertainties and opportunities *Health Policy* 121 477-480, at p 478 Available from: [http://www.healthpolicyjrn.com/article/S0168-8510\(17\)30062-3/pdf](http://www.healthpolicyjrn.com/article/S0168-8510(17)30062-3/pdf) [Accessed June 5 2017]

⁶¹ One possible way to resolve this is by way of the 'opt out' mechanism contained in the WTD. This mechanism operates whereby an individual, on a voluntary basis, elects to sign a waiver with their employer agreeing that they are happy to work additional hours. It is important to note that it is not possible to opt out of the rest requirements, so doctors would still need to ensure they take the necessary breaks, and their employer would still need to monitor the hours they work. Opt Out is not unique to the UK and other EU countries permit a broad use of Opt Out, for example, Bulgaria, Cyprus, Estonia & Malta. Other members permit the Opt Out but only in relation to certain occupations, including health care sectors. For example, Belgium, Czech Republic, France, Germany, Hungary, Latvia, the Netherlands, Poland, Slovakia, Slovenia and Spain.

⁶² *Agenda for Change*, implemented on 01 October 2004, represents a major reform of pay and other terms and conditions for all NHS staff with the exception of Medical and Dental Staff and some Senior Managers. It is the first significant reform of NHS pay since the Health Service was established in 1948. See in summary- <http://www.msg.scot.nhs.uk/pay/agenda-for-change/afc-in-summary> [Accessed July 13 2017]

58. As noted above, the management of the NHS Scotland is generally devolved to the health boards. However, they do not operate independently of the Scottish Government and national service guidelines and protocols play an increasingly important role in the practise of 'evidence based' medicine. NHS Health Improvement Scotland (HIS) is the umbrella organisation for setting standards of care and incorporates organisations such as the Scottish Intercollegiate Guidelines Network (SIGN) which produces guidelines on clinical practice and the Scottish Medicines Consortium (SMC) advises boards on the clinical and cost-effectiveness of newly licensed medicines. The SMC does not however currently licence medicines in Scotland. This is undertaken by the Medicines and Healthcare products Regulatory Agency (MHRA - the licensing body for the UK) or the European Medicines Agency (EMA - the licensing body for the European Union).

The European Medicines Agency (EMA)

59. The EMA is the largest EU organisation residing in the UK. It has an annual budget of 331.1 million Euros, employs 900 staff and attracts 35 million expert visitors to its offices annually.⁶³ Since 1995, its base in London provides a centralised approach to the regulation of human and veterinary medicines and clinical trials. This means that, for example, pharmaceutical companies only need to submit a single application for the EMAs approval, which if given, centrally authorises marketing in not only the EU but through the EEA Agreement, it also includes Norway, Iceland and Lichtenstein.

60. On 2 May 2017 the EMA published a notice to holders of such an authorisation acknowledging that the UK's notification to withdraw from the Union will mean that (subject to other agreements or extensions)

*'...all Union primary and secondary law ceases to apply to the United Kingdom from 30 March 2019, 00:00h (CET). **The United Kingdom will then become a 'third country'.***⁶⁴

This will affect not only nation states but private companies and the question will be how the 'third country' status will affect the UK.

61. Many remaining states have already expressed an interest in hosting the EMA⁶⁵ ⁶⁶ understandably seeing its potential as an employer, the access it provides to frontline research and the general

⁶³ Financial Times (Jan 3 2017) London-based regulator for EU drugs fears staff exodus. Available from : <https://www.ft.com/content/2ca416ba-c8f8-11e6-8f29-9445cac8966f> [Accessed June 15 2017]

⁶⁴ Authors insertion in bold. European Medicines Agency (2017) Questions and Answers related to the United Kingdom's withdrawal from the European Union with regard to the medicinal products for human and veterinary use within the framework of the Centralised Procedure. P.1. Available from: http://www.ema.europa.eu/docs/en_GB/document_library/Other/2017/05/WC500228739.pdf [Accessed June 15 2017]

⁶⁵ New Statesman (April 2017) What happens when the European Medicines Agency leaves the UK? Available from: <http://www.newstatesman.com/print/node/307581> [Accessed June 15 2017]

prestige that accompanies it. The relocation decision will be made by EU heads of state, meeting as the European Council.⁶⁷ At time of writing, a decision on the location of the EMA is expected in October.⁶⁸

62. For the UK, as well as the loss of an organisation as a substantial employer, would be the impact of loss of access to the single market authorisation. This may result in additional time-consuming process, isolation and extra expense with medicinal companies choosing to relocate within an EEA country.⁶⁹ For example, a marketing authorisation holder, such as a pharmaceutical company, currently established in the UK, would need to transfer its marketing authorisation to a holder established in the Union (EEA).⁷⁰ Similarly, if the manufacturing site of a finished medicinal product is located within the UK, from the date of withdrawal from the Union, they will be considered 'imported medicinal products.'⁷¹ Small and medium size enterprises (SMEs) would also lose access to the financial and administrative assistance that they currently receive.⁷² This may include smaller biotech companies residing in the UK who may then lack the capacity to file multiple applications.⁷³

63. A major concern is that the above would result in delays to accessing new treatments and medications.⁷⁴

64. A possible resolution post March 2019, would that the EMA would maintain a partnership with the UK domestic regulatory agency; the MRHA, allowing for mutual recognition of medicine approvals. It currently makes a major contribution to the EMA, taking the lead in approving 20% of all

⁶⁶ Baker MacKenzie (2017) Brexit- What it means for your business. Available from: <http://brexit.bakermckenzie.com/2017/04/12/brexit-healthcare-update/> [Accessed June 15 2017]

⁶⁷ Their decision has to be unanimous. Reuters Business news (April 2017) With Brexit underway , EU drugs agency prepares to leave London. Available from: <http://www.reuters.com/article/us-britain-eu-pharmaceuticals-idUSKBN1771XM> [Accessed June 15 2017]

⁶⁸ Rankin J (2017) EU countries compete to host London-based agencies after Brexit . **The Guardian**. Available from: <https://www.theguardian.com/world/2017/jun/22/eu-countries-compete-to-host-london-based-agencies-after-brexit> [Accessed July 17 2017]

⁶⁹ See for example, the New Statesman who argued that Japan believed that the current location EMA enhanced the UK's reputation for frontline scientific development. New Statesman (April 2017) What happens when the European Medicines Agency leaves the UK? Available from: <http://www.newstatesman.com/print/node/307581> [Accessed June 15 2017]

⁷⁰ see Commission Regulation (EC) 2141/96. A similar procedure would apply to an orphan medicinal product.

⁷¹ The competent authorities of the Union (EEA) shall ensure that the import of medicinal products into their territory is subject to an authorisation in accordance with Article 40(3) of Directive 2001/83/EC and Article 44(3) Of Directive 2001/82/EC. The authorisation is granted when a number of conditions, as defined in Articles 41 and 42 of Directive 2001/83/EC and Articles 45 and 46 of Directive 2001/82/EC, are fulfilled (e.g. availability of a qualified person within the Union (EEA), GMP inspection). It would also have to comply with additional regulations for quality and batch control.

⁷² Known as the 'SME regulation'- Commission Regulation (EC) No 2049/2005

⁷³ This point was made in the House of Common debate on EMA last October. Hansard (12 October 2016) House of Commons Debate on European Medicines Agency. Available from: <https://hansard.parliament.uk/commons/2016-10-12/debates/C1A87D11-1F3E-4BAF-8DC0-2023B96AD963/EuropeanMedicinesAgency> [Accessed 16 June 2017] at p.2

⁷⁴ Noting that Uk residents have access new treatments and drugs up to 6 months earlier than, for example, Canada and Australia. A point also made in the House of Commons debate on the EMA in October 2016

medicines in the EU⁷⁵ and has been described as having a ‘symbiotic’⁷⁶ working relationship with the EMA. This would not resolve the concerns that a separate application from pharmaceutical companies to the MHRA would be time consuming and a ‘less efficient regulatory process’.⁷⁷ The MHRA’s business plan for 2017-18 makes it clear that they are aware of the challenges in progressing their post-date Brexit strategy and a top priority is to;

‘[D]evelop consensus around a proposed model for future regulation of medicines and medical devices in the UK, post Brexit which protects public health, facilitates innovation and minimises burden on industry in order to influence and support HMG negotiations and make the UK an attractive global regulator.’⁷⁸

65. Another possible option for the UK is to adopt an independent system for authorising and licensing medicines and medical devices but one of cooperation in the enhancement of public health through sharing of information. Switzerland has a confidentiality agreement with the EMA and the European Commission’s Directorate general for Health and Food safety, the Swiss Agency for Therapeutic Products (Swissmedic) and the Swiss Federal Dept. for Home Affairs. It covers the sharing of non-public information in order to enhance public health protection. This has been in place since July 2015 and is valid for five years.⁷⁹ It complements a mutual recognition agreement between the EU and Switzerland which regulates the areas of quality and manufacturing. Swiss regulation therefore follows EU regulation in many areas. However, there is no automatic recognition of marketing authorisations granted by the EU. Marketing authorisations are granted by Swissmedic and includes the supervision of clinical trials. Account is taken of other comparable marketing authorisation systems, including, for example, the EU or USA.
66. It therefore remains to be seen whether the role of the Scottish Medicines Consortium would change to become a licensing authority in its own right or support an enhanced role for the MHRA.

⁷⁵ Reuters Business news (April 2017) With Brexit underway , EU drugs agency prepares to leave London. Available from: <http://www.reuters.com/article/us-britain-eu-pharmaceuticals-idUSKBN1771XM> [Accessed June 15 2017]. Some commentators place this even higher .

⁷⁶ Hansard (12 October 2016) House of Commons Debate on European Medicines Agency. Available from: <https://hansard.parliament.uk/commons/2016-10-12/debates/C1A87D11-1F3E-4BAF-8DC0-2023B96AD963/EuropeanMedicinesAgency> [Accessed 16 June 2015] at p. 2

⁷⁷ Hansard (12 October 2016) House of Commons Debate on European Medicines Agency. Available from: <https://hansard.parliament.uk/commons/2016-10-12/debates/C1A87D11-1F3E-4BAF-8DC0-2023B96AD963/EuropeanMedicinesAgency> [Accessed 16 June 2015]

⁷⁸ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/637000/Agency_Business_Plan_2017-18_v1.2_-_final_.pdf
⁷⁹ European Medicines Agency- Switzerland (2017) Available from : http://www.ema.europa.eu/ema/index.jsp?curl=pages/partners_and_networks/document_listing/document_listing_000262.jsp&mid=WC0b01ac058009b148 [Accessed July 17 2017]

Nuclear medicine; diagnostic and treatment

67. The UK Government has announced its intention to leave the European Atomic Energy Community (Euratom) as part of the Brexit process. This was first announced within the explanatory notes⁸⁰ which accompanied the European Union (Notification of Withdrawal) Bill 2016-17.

68. Nuclear technology is used for the diagnosis and treatment of cancer. British nuclear reactors cannot produce radioisotopes, which form the core material for nuclear treatment. Hinkley Point C will have the ability to produce medical radioisotopes, however this will not come on line until around 2027. Currently radioisotopes, which have a very short lifespan, are sourced and provided by the Euratom Supply Agency (ESA) which facilitates easy access and transfer of nuclear diagnostic and medicinal nuclear material speedily across the EU. Withdrawal from the Euratom raises major concerns of the supply and availability of this life-saving material.

69. There is a serious concern that the early diagnosis and treatment of cancer will be greatly affected by leaving the Euratom. This concern is shared by, amongst others, The Royal College of Radiologists;

“The Royal College of Radiologists, like others in medicine and industry, is seriously concerned about continued access to these materials if we leave the Euratom treaty under Brexit”⁸¹

70. It is vitally important that Brexit negotiators ensure that the access and availability of nuclear health materials is safeguarded.

Staffing

71. Current challenges regarding staffing of the NHS tend to be interrelated and centre around shortage of staff, working conditions and low morale. Within the UK as a whole, the NHS faces difficulties in recruiting and retaining permanent staff. The UK has a ratio of 278 doctors per

⁸⁰ <https://publications.parliament.uk/pa/bills/cbill/2016-2017/0132/en/17132en.pdf>

⁸¹ <https://www.rcr.ac.uk/posts/rcr-statement-potential-impact-leaving-euratom-treaty>

100,000 of the population compared to an EU average of 347 per 100,000.⁸² Similar problems can be seen in the social care sector not only in relation to vacancy rates but also high turnover.⁸³

72. The EU's legislative underpinning of freedom of movement and mutual recognition of professional qualifications within the EU provides for health and social care professionals from other EU countries to work within the NHS. Following Brexit, this will no longer apply. This may deter those who are considering moving to the UK as well as having, as yet unknown, implications for those already working in the UK.

73. The GMC records show that about 11% of doctors registered in the UK gained their professional qualifications from another EEA country.⁸⁴ 5.8% of doctors in Scotland are recorded as qualified in another EU country, but this does not take account of EU citizens who trained in Scotland so the real number is likely to be higher.⁸⁵

74. Section 6.3 of the UK Government's White Paper on Brexit and future partnership with the EU aims to 'secure the status of EU nationals currently in the UK'⁸⁶. To this end, a policy paper was published as a UK Government paper on 26 June 2017 which set out proposals for safeguarding the position of EU citizens living in the UK and UK nationals living in the EU.⁸⁷ The policy paper proposes that EU citizens living in the UK will qualify for 'settled status'⁸⁸ if they have been continually resident in the UK for five years.

75. It also promises to protect access to UK pensions, economic and other rights and these will be addressed in other sections of this paper.⁸⁹ At time of writing, calls for clarity have been made, for

⁸² Cylus, J et al (2015) United Kingdom Health System Review. Health Systems in transition. 17 5 1-126.

⁸³ The King's Fund(2016) *Five big issues for health and social care after the Brexit vote* Available from: <https://www.kingsfund.org.uk/publications/articles/brexit-and-nhs> [Accessed June 5 2017]

⁸⁴ Letter to the Editor(2017) Brexit and the NHS: Challenges, uncertainties and opportunities *Health Policy* 121 477-480, at p 477 Available from: [http://www.healthpolicyintl.com/article/S0168-8510\(17\)30062-3/pdf](http://www.healthpolicyintl.com/article/S0168-8510(17)30062-3/pdf) [Accessed June 5 2017]

⁸⁵ Robson K, (2016) , '*The National Health Service in Scotland*' Scottish Parliament SPICe '*The National Health Service in Scotland*' at p.3. Available from: http://www.parliament.scot/ResearchBriefingsAndFactsheets/S5/SB_16-100_The_National_Health_Service_in_Scotland.pdf [Accessed 30 May 2017]

⁸⁶ Dept. For Exiting the European Union (2017) The United Kingdom's exit from and new partnership with the European Union. Available from: <https://www.gov.uk/government/publications/the-united-kingdoms-exit-from-and-new-partnership-with-the-european-union-white-paper/the-united-kingdoms-exit-from-and-new-partnership-with-the-european-union--2> [Accessed June 5 2017]

⁸⁷ HM Government. (2017) The United Kingdom's Exit from the European Union Safeguarding the Position of EU Citizens Living in the UK and UK Nationals Living in the EU. Available from: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/621847/60093_Cm9464_NSS_SDR_Print.pdf [Accessed July 12 2017]

⁸⁸ This is defined in the Government paper as 'indefinite leave to remain pursuant to the Immigration Act 1971'. Summary Proposals Principle 6.

⁸⁹ Ibid- Principle 7.

example, whether students, who will be allowed to stay in the country to finish courses, will be able to remain to work after the completion of their studies.⁹⁰

Procurement, state aid and competition within the NHS

76. Procurement law in the European Union and the European Economic Area (EEA) is based on three EU Directives (adopted also by the EEA), of which two (Directive 2014/23 on public procurement and Directive 2014/32 on public concession contracts) are relevant to health services.
77. The Public Contracts Directive implements the World Trade Organization's Agreement on Government Procurement (GPA) but, along with the Public Concessions Directive, it goes wider: it applies to procurement not only by organs of central government but also by "contracting authorities" - bodies owned or controlled by public authorities (or their appointees) and is much more detailed and comprehensive.
78. Organs of central government have lower application thresholds (in line with GPA requirements). The directives are in turn implemented by Scottish Statutory Instruments (SSIs), the Public Contracts (Scotland) Regulations 2015 and the Concessions Contracts (Scotland) Regulations 2016. These include provisions classifying Health Boards, Health Improvement Scotland and Health and Social Care Partnerships as organs of central government). The Procurement Reform (Scotland) Act 2014 and the Procurement (Scotland) Regulations 2016 also apply (with much lower thresholds) but do not implement any EU law. That is the situation for procurement by health service providers.
79. Procurement of health service provision from an external entity that provides it for a fee (an "undertaking" in competition law) is different. The Procurement Reform (Scotland) Act 2014 and the Procurement (Scotland) Regulations 2016 do not apply to procurement of health services. The EU-driven procurement regime does apply but with a "light touch" and special extra-high thresholds. Unlike the separate legislation of England & Wales and Northern Ireland, the Scottish EU-implementing legislation did not take up the directive's option of creating a special privileged position for social enterprises providing health or social care. Procurement law does not apply to provision by wholly-owned subsidiaries of a contracting authority so long as they operate as its

⁹⁰ Boffey, D. (2017)

Citizens' rights: EU chief Brexit negotiator calls for more clarity from UK The Guardian. Available from:

<https://www.theguardian.com/politics/2017/jun/26/citizens-rights-eu-chief-brexit-negotiator-calls-for-more-ambition-from-uk> [Accessed July 20 2017]

“quasi departments” and almost their entire activity consists of serving its needs. Such companies are sometimes referred to as Arm’s Length External Organisations (ALEOs).

80. EU (and EEA) state aid law can apply to any entity (private or public, for profit or not-for-profit) that provides services for a fee (an “undertaking”) but it does not apply if the recipient is part of a social solidarity system and truly receiving a grant, rather than a fee. Like procurement and state aid law, other EU competition law (anti-competitive practices, abuse of market dominance, mergers) also applies only to “undertakings”. NHS provider licences are not EU driven and the competition status of entities subject to them is outside the scope of this paper.

81. Association agreements between the EU and third countries normally replicate the essentials of EU competition (including procurement and state aid) requirements.

Cross border cooperation - Spread of disease and collaborative research

82. Such cooperation is essential to ensure that effective early warning systems are in place and able to respond to the diverse health threats. *‘Cross-national approaches to public health are essential when dealing with issues that do not stop at a country’s borders...’*⁹¹

83. **European Centre for Disease Prevention and Control.** As well as playing an important role in a range of public health issues, the EU operates systems for the surveillance and early warning of communicable diseases, managed by the European Centre for Disease Prevention and Control, which is currently located in Sweden. These facilitate the rapid sharing of information and technical expertise in response to potential pandemics, communicable diseases and other cross-border health threats. Health protection in Scotland is self-contained but still reliant on international networks and networking. It remains to be seen if the UK will decide to establish a separate body for the surveillance and early warning of communicable diseases. This would seem to be a problematic decision unless some collaborative measures were put in place, as the prevention of the spread of disease relies on shared and effective ‘early warning’ mechanisms. One option would be to adopt a similar model to Switzerland which has a confidentiality agreement with the various EU agencies to facilitate the sharing of non public information to enhance public health protection.⁹² Again this may mean new arrangements with the associated devolved organisations and agencies within the UK.

⁹¹ Majeed, A (2017) ‘What impact will Brexit have on public health and health services in the United Kingdom?’ *Better Health For All*. Available from: <https://betterhealthforall.org/2017/03/06/what-impact-will-brexit-have-on-public-health-and-health-services-in-the-united-kingdom/> [Accessed 30 May 2017]

84. **Research:** General themes point to a rise in EU academics leaving British universities with the reasons centred on three reoccurring concerns:
1. status and rights of EU national academic staff,
 2. access to EU research funding and
 3. the perception that the UK is becoming a less welcoming place to work⁹³.
85. The creation of boundaries and country specific institutions may lead to stagnation in areas such as medical research. Collaboration across the EU has enabled the UK to further its scientific research agenda, through its ability to access both European research talent and important sources of funding. Collaboration and targeted funding are the cornerstones of today's research environment. The current EU science programme, Horizon 2020, has provided some 80 million euros in research funding world-wide. The UK is involved in more research initiatives than any other member state and has led more health related projects than any other country.⁹⁴ Between 2007 and 2013 the UK contributed 5.4 billion euros to EU research and received 8.8 billion euros.⁹⁵
86. There are also other formal and informal networks across Europe – for example for some rare diseases, where the low numbers affected make it beneficial to work across the EU. Academic communities have particular concerns and Professor Rutam Al-Shahi Salman, from the University of Edinburgh, believes that '*Brexit will immediately destabilise our ongoing EU funded multi-centre studies*'⁹⁶ However, in the shorter term, the UK government has guaranteed to underwrite some of the funding programmes⁹⁷ which will go some way to providing reassurance but providing funding does not necessarily bring with it an automatic right to contribute to policy.

Access to treatment both in the UK and the EU

⁹³ Skovgaard-Smith I (2017) How European academics are feeling about life in Britain a year after Brexit vote. **The Conversation**. Available from: <https://theconversation.com/how-european-academics-are-feeling-about-life-in-britain-a-year-after-brexit-vote-78687> [Accessed 13 July 2017]

⁹⁴ McKee, M Galsworthy M, J. (2016) Brexit: a confused concept that threatens public health. *Journal of Public Health* at p. 4 Available from: https://oup.silverchair-cdn.com/oup/backfile/Content_public/Journal/jpubhealth/38/1/10.1093_pubmed_fdv205/2/fdv205.pdf?Expires=1496410173&Signature=DEBTyL0fkXGAviVNJ-e7Bd9QRKyvPLcyWrxCRlojxc9lqLTnjXZGrVX-pSi-UPOAQCScDbvTbEmi9QtM90M2Ru--BR-cpg76tDB4-GRtMF62maAXjiOungVx3vEjblo3flcG3UOGcxuajrTivFFMXVqBnVI-ce3ciZqvXi7dlLyMsU2I-Adx5dYMu1y70-eB-rDbtJL6Q2s3e0qrMddKTeMojKwIP-5N-mnRVe591ACBi9fnRjN2SCKTJABdLeWecd9rg0U6V6TunNCIPYBgbucgk2GIB0Jh4g7aaKL-V1-TTM09k48TaNsU3VG7w4HBuE9VXGpOhVAXauDYGDj1g_&Key-Pair-Id=APKAIUCZBIA4LVPAVW3QH [Accessed June 16 2017]

⁹⁵ The King's Fund (2016) *Five big issues for health and social care after the Brexit vote* Available from: <https://www.kingsfund.org.uk/publications/articles/brexit-and-nhs> [Accessed June 5 2017]

⁹⁶ McCabe, S., (2016) *Brexit and the NHS* Available from: <https://iscot.scot/brexit-and-the-nhs/> [Accessed 23 May 2017]

⁹⁷ ...for example the Horizon 2020 programme...

87. Cross-border health care is one of the most direct ways that citizens of the UK and across the EU will feel the impact if existing collaborative and reciprocal arrangements cease to have effect. There are around 1.2 million UK migrants living in other EU countries, compared with around three million EU migrants living in the UK⁹⁸ and there are concerns that the referendum result will mean that UK pensioners currently living elsewhere in the EU may return, increasing pressures on health and social care services. The Nuffield Trust suggests that the cost per head in the UK for the treatment for those aged over 65, is £4,950 per year.

‘As the NHS has never been very effective in reclaiming the fees owed to it by overseas visitors to the UK, the UK may find itself substantially worse off financially when new arrangements for funding cross-national use of health services are put in place.’⁹⁹

88. There are a number of routes for citizens resident in the UK to obtain medical treatment in another EU state. For example:

- d) The EHIC is designed to cater for the unplanned health needs of tourists. This is for emergencies and covers only treatment provided by the state as opposed to private treatment ;
- e) The “S2 route” in which, after prior authorisation has been obtained by the patient, the UK pays the other state directly to provide particular treatment. This also is restricted to state health care. The patient has to pay any contribution to the costs that a local citizen in the other state would have had to pay. In some countries this could amount to 25% of costs;
- f) The rights arising from Directive 2012/52/EU¹⁰⁰ to treatment in another state, including private treatment, although the patient must pay upfront and apply to be reimbursed. In this case prior authorisation from the UK health authority is also required in some circumstances.

89. For UK nationals who are permanently resident in another EU state, the possibilities are:

- c) For those in receipt of an “exportable benefit” (most commonly retirement pension), they are likely to qualify for state health care in the country of residence, paid for by the UK;
- d) Other UK nationals need to apply to the state in which they are resident and will be entitled to state-provided health care from that state on the same basis as nationals of that country.

⁹⁸ Migration Watch UK (2016) *The British in Europe and Vice Versa*. Available from: <https://www.migrationwatchuk.org/briefing-paper/354> [Accessed 19 June 2017]

⁹⁹ Majeed, A (2017) ‘What impact will Brexit have on public health and health services in the United Kingdom?’ *Better Health For All*. Available from: <https://betterhealthforall.org/2017/03/06/what-impact-will-brexit-have-on-public-health-and-health-services-in-the-united-kingdom/> [Accessed 30 May 2017]

¹⁰⁰ Available from: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0052> [Accessed 19 June 2017]

Clearly, all of these routes to cross-border health care are vulnerable and their future implementation uncertain.

90. A line of ECJ case law had gradually established that EU citizens of one country had the right to travel to other EU states to receive medical treatment and that the patient should not have to pay. The circumstances surrounding reimbursement of medical costs incurred overseas remained unclear. Some answers were provided by the ECJ in the 2006 case of *Yvonne Watts v Bedford Primary Care Trust*¹⁰¹. A British NHS patient had gone to France for a hip replacement because of the long waiting list at her local health authority. At home she was refused reimbursement of her costs. The ECJ considered that the Treaty on freedom to provide services included this particular set of circumstances and held that a national waiting list could not be used to justify withholding rights to cross-border treatment. It also settled the question of whether cross-border rights applied only between insurance-based systems as some had previously maintained. The court held that taxpayer-funded systems such as the NHS were also subject to these rights.

91. Following this case the Directive 2011/24/EU¹⁰² of the European Parliament and of the Council on patients' rights in cross-border health care was issued and implemented in Scotland by The National Health Service (Cross-border Health Care) (Scotland) Regulations 2013. These were amended in 2015 to facilitate recognition of medical prescriptions between member states.¹⁰³ The National Health Service (Cross-border Health Care) (Scotland) Regulations 2013 provide for reimbursement of costs of health care in another EEA country to which the patient has specifically travelled for the purpose of receiving that treatment. The entitlement is to private or state health care. Reimbursement is up to the level of the costs which would otherwise have been borne by the home country. Importantly, reimbursement is only for treatment which is the same or equivalent to treatment to which the patient would have been entitled at home. This rules out some treatments, for example, proton beam therapy, available in Europe for a wider range of conditions than in the UK.

92. Prior authorisation from the home health board is required if an overnight stay in hospital or the use of highly specialised equipment is involved or in cases of particularly high risk. The health board

¹⁰¹ *Yvonne Watts v Bedford Primary Care Trust* C-372/04

¹⁰² <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=LEGISSUM:sp0002>

¹⁰³ The National Health Service (Cross-border Health Care) (Scotland) Directions 2015 also instructed health boards on various standards and procedures to be adopted, for example in "undue delay" and telemedicine cases.

can refuse authorisation if the treatment can be provided at home within a “medically justifiable” time limit, opening up the issue to a spectrum of medical opinion as to the appropriate waiting time for treatment in any individual case and potentially diluting the patient’s ability to avoid the waiting list at home.

93. The perception is that this route to treatment is less widely used than the others. Although the regulations contain a requirement to set up a national contact point giving information on access to health care in the EU, this route may be too little known as yet. The requirement to pay upfront and apply to be reimbursed is probably also a considerable disincentive for some patients.
94. Apart from conferring the above rights to cross-border health care, Directive 2012/52/EU supported other initiatives, albeit in a less prescriptive fashion. It was somewhat visionary in its ambitions for coherent European health care and medical and scientific co-operation. It promoted European Reference Networks and centres of excellence to enhance co-operation to develop a better capacity for the diagnosis and treatment of rare diseases and the use of telemedicine.
95. At the time of writing and following the most recent negotiations, it has been agreed¹⁰⁴ that the existing reciprocal arrangements will continue in relation to the European Health Insurance Card (EHIC). This will apply to EU citizens in the UK and UK citizens currently residing in an EU state whether they are studying, working or retired. This will be the case if you are resident in an EU country on the day that the UK leaves the EU. However, for UK or EU citizens who wish to travel and avail themselves of these arrangements, the position is currently less clear. The EU wishes to see further progress made on separation agreements before future arrangements can be negotiated.

Conclusions

96. Views are divergent whether the risk to the provision of health care and public health policy comes from within the UK domestic politics or from outside the UK. Perhaps it would not be unreasonable to say that Brexit has done nothing so far to improve this situation. The prevailing theme, at least for the moment, is that there will be less money available for the NHS after Brexit.

¹⁰⁴ European Commission Task Force for the Preparation and Conduct of the Negotiations with the United Kingdom under Article 50 TEU and the UK. Available from: file:///C:/Documents%20and%20Settings/abri/My%20Documents/Downloads/joint_table_citizens_rights_-_third_round.pdf [Accessed 5 September 2017] TF50 (2017) 16 - Commission to EU27 at p. 11 ‘Healthcare –personal scope’.

97. As time progresses and deadlines approach and are passed, the continuing lack of clarification on many of the issues discussed in this paper continues to destabilise relationships, put a strain on the rights of current and future healthcare care staffing and on the future roles of the diverse but interrelated organisations that currently exist.
98. The UK economy and the NHS are inextricably linked and the prolonged uncertainty of what the Brexit terms will entail continues to reverberate. It is important to remember that these terms will not just affect the UK but the remainder of the EU states.
99. However, the reality is, regardless of Brexit, that the NHS requires support, both financial and strategic, just to maintain its current structure. Audit Scotland notes in its 2016 report that '*NHS boards are facing an extremely challenging financial position*'.¹⁰⁵
100. As noted earlier, within the provisions with in the European Union (Withdrawal) Bill 2017-19¹⁰⁶ the UK government can utilise the EU law which it believes works well and amend or repeal those areas and replace them with structure which will be advantageous to the NHS.
101. The problem is that there will be costs attached to that approach since it is possible that the remaining EU states would insist that the UK would need to pay to participate and share in EU structures without necessarily having any say.

Recommendations

102. There are now signs that 'alliances' of shared interests are being formed across many areas including health, the Brexit Health Alliance¹⁰⁷ being but one such initiative. We recommend that continuous monitoring will be vital to ensure that UK negotiating positions appreciate a clear understanding of the Scottish arrangements regarding health and the implications of withdrawal.
103. Many of these initiatives and alliances of shared interests will unsurprisingly take a broad UK perspective and we recommend that Scotland's healthcare provisions and business structure should be viewed as distinctive.

¹⁰⁵ Audit Scotland (2016) *NHS in Scotland* 2016 Available from: http://www.audit-scotland.gov.uk/uploads/docs/report/2016/nr_161027_nhs_overview.pdf [Accessed 23 May 2017]

¹⁰⁶ <http://services.parliament.uk/bills/2017-19/europeanunionwithdrawal.html>

¹⁰⁷ http://www.amrc.org.uk/sites/default/files/doc_lib/Brexit%20Health%20Alliance%20Asks.pdf

104. We recommend that the relevant stakeholders in Scotland should promote a clear understanding and promotion of how its organisations are currently structured, their existing strengths and future priorities.
105. The regulation of health by the EU can be understood within a thematic approach to policy making. We recommend that scrutiny be given to ascertain overall costs and benefits of existing EU regulation.
106. We recommend consideration be given as to how individual states, both within and out with the EU, have implemented or incorporated EU health regulation with a view to workable post Brexit, options for the UK.
107. Medical licensing remains a major concern and the UK has to be a decision on how it will licence medicines in the UK once it leaves the European Medicines Agency. We recommend an evaluation of the existing contributions and alignments from major organisations such as the MHRA as well as a review of the role of other organisations which have, to date, not played a part.
108. We recommend that Brexit negotiations ensure that the access and availability of nuclear health materials is safeguarded.
109. Health care coverage is a highly visible priority for UK citizens. Whilst it has been agreed that the existing reciprocal arrangements will continue in relation to the European Health Insurance Card (EHIC) for those resident in EU states prior to the Brexit date, for UK or EU citizens who wish to travel and avail themselves of this arrangement post Brexit the position is currently less clear. We recommend that negotiations are given priority in this area and reciprocal and mutually beneficial arrangements for health care coverage and maintaining cross border healthcare are progressed.
110. Health research is another area which succeeds on the basis of strong networks producing excellence and innovation within the health related disciplines. These networks are already fracturing. We recommend that the UK and EU seek ways to preserve the major contribution that the UK currently makes to research within the EU. We believe that given the willingness of those who work in this area, current negotiations may provide an opportunity to foster new relationships and stronger collaboration in the future.

111. In April 2017, the UK Parliament's Select Committee on Health published its report on the potential impact of the UK withdrawal.¹⁰⁸ It suggested that *'[T]he Department of Health produce a comprehensive list of those issues that will require contingency planning.'*¹⁰⁹ The Scottish Parliament has not conducted any similar inquiry to consider issues from a Scottish health and social care perspective. We recommend that they should undertake such an inquiry.

¹⁰⁸ **Brexit and health and social care—people & process. (April 2017)** Available from:
<https://publications.parliament.uk/pa/cm201617/cmselect/cmhealth/640/64002.htm> [Accessed Sept 2 2017]

¹⁰⁹ **Brexit and health and social care—people & process. (April 2017)** para 6. Available from:
<https://publications.parliament.uk/pa/cm201617/cmselect/cmhealth/640/64002.htm> [Accessed Sept 2 2017]



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