Published 10 May 2018
SP Paper 314
4th Report (Session 5)

The Scottish Parliament
Pàrlamaid na h-Alba

## Health and Sport Committee
## Comataidh Slàinte is Spòrs

# The impact of leaving the European Union on health and social care in Scotland.

**Published in Scotland by the Scottish Parliamentary Corporate Body.**

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# Contents

**Introduction** 1
Background 1
**Impact on the public and public health** 3
NHS funding 3
Reciprocal healthcare 4
European Health Insurance Card (EHIC) 4
S1 scheme 5
Public health 6
Standards, regulations and trade deals 6
Surveillance and the European Centre for Disease Protection and Control 8
**Impact on professionals** 10
Recruitment and retention of staff 10
Research workforce and collaboration 13
Recognition of qualifications, the regulation of professionals and minimum training requirements 14
Planning for Brexit 16
Working time directive 17
**Impact on research and clinical trials** 18
Research funding 18
Clinical trials regulation and access 19
**Impact on medicines and devices** 21
Medicines 21
Regulation 21
Pharmacovigilance 23
Medical isotopes and EURATOM 24
Medical device regulation 25
**Common UK frameworks** 27
**Conclusions** 30
**Annexe A - Minutes of meeting** 31
**Annexe B - Evidence** 33
Written evidence 33
Official reports 34
**Bibliography** 35

# Health and Sport Committee

To consider and report on matters falling within the responsibility of the Cabinet Secretary for Health and Sport.

http://www.scottish.parliament.uk/parliamentarybusiness/CurrentCommittees/health-committee.aspx

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# Introduction

1. On 23 June 2016 the UK voted to leave the European Union. The leave date has been set for 29 March 2019.

2. Under the EU Treaties, the protection and improvement of human health is an area where the EU has supporting competence, meaning that it can only intervene to support, coordinate or complement the action of EU Member States.

3. This means delivery of Member States health policies has little direct involvement from the EU. However, policies such as the single market and freedom of movement legislation mean the EU is indirectly involved with health issues. Knock-on effects to healthcare provision are likely to result from changes to trade, economic and immigration policy in particular.

4. The impact of leaving the EU (Brexit) on health and social care in Scotland is difficult to predict and will remain unknown until at least the final withdrawal terms are agreed. However we wanted to identify potential risks and consider how they could be mitigated and potential opportunities could be realised.

5. Within the UK, health policy is largely the responsibility of the devolved nations. This includes public health and the NHS. Scotland has developed its own distinct laws and policies.

# Background

6. On 28 November 2017 we agreed to hold an inquiry into the implications of leaving the EU on health and social care in Scotland.

7. We had considered the general implications of Brexit on a number of occasions this session and noted these in a letter to the Culture, Tourism, Europe and External Relations Committee. This letter also identified the areas we considered most likely to be affected by Brexit.

8. Further areas with a potential impact on health and social care in Scotland were identified in a letter from the Minister for UK negotiations on Scotland's place in Europe to the Finance and Constitution Committee. These included:

   - blood safety
   - data protection
   - food compositional standards/labelling
   - funding
   - good laboratory standards
   - mutual recognition of professional qualifications
   - new medicines and clinical trials

- organs
- procurement
- public health
- reciprocal healthcare
- research and life sciences
- tissue
- tobacco
- workforce

9. We issued a call for evidence which ran from 11 December 2017 to 25 January 2018. This sought views on the possible risks and benefits of Brexit whilst also seeking views on future trade agreements and common frameworks. We received 43 written responses including one from the Cabinet Secretary for Health and Sport.

10. The Scottish Parliaments Information Centre (SPICe) published a briefing on the possible implications of Brexit on health and social care in Scotland on 30 January 2018. This was followed by a briefing seminar on 7 February 2018 with speeches from Professor Jean McHale, Prof of Health Care Law from Birmingham law school and Professor Alison Britton, Professor of Healthcare and Medical Law, Glasgow Caledonian University and Convenor of the Health and Medical Law Sub Committee for the Law Society of Scotland.

11. We held oral evidence sessions on 6 March and 13 March with stakeholders and then on 20 March with the Cabinet Secretary for Health and Sport. Lord O'Shaughnessy, Parliamentary Under Secretary of State for Health was also invited to attend to give evidence. However he was unable to attend the various dates offered. These sessions focussed on:

- the impact on the public and public health
- the impact on professionals
- the impact on research and clinical trials
- the impact on medicines and devices

# Impact on the public and public health

12. This section of the report will consider the possible impact of Brexit on the public, looking at the potential impact of funding pressures, the future of reciprocal health care and potential impacts on wider public health in Scotland.

## NHS funding

13. The UK's vote to leave the EU could have significant indirect implications for health and social care in Scotland, not least because it has ushered in a period of economic and political uncertainty at a time when the health and social care system is already facing operational and financial pressures.

14. A number of submissions to our call for views commented on a possible domestic economic downturn post-Brexit and its potential impact on the funding of the public sector including the NHS. Who Cares? Scotland noted a reduction in national income would impact on vulnerable groups in society such as care experienced people who depend on services provided by local authorities, the public sector and third- sector organisations. [1]

15. BMA Scotland noted "there is a growing gap between the demand for health and social care services in Scotland, and the resources available to deliver them. With ongoing uncertainty over trade agreements, and downgraded growth forecasts, there is a clear possibility this could lead to reduced levels of spending on public services. If this leads to cuts at Westminster, and a reduction in Scotland's budget, there clearly remains a very real threat to NHS spending in Scotland, which would only exacerbate the funding gap" [2]

16. During oral evidence the Nuffield Trust advised:

> Perhaps the clearest estimate of the impact on public finances is from the Office for Budget Responsibility in London, which sets the UK Government's expected income for future years. It thinks that there will be about £15 billion less in the Treasury by 2020 as a result of the UK leaving the European Union...You would expect that to feed through, more or less one for one, into the public finances.
>
> Source: Health and Sport Committee 06 March 2018, Mark Dayan (Nuffield Trust), contrib. 4[1]

17. Prior to the referendum there were already increasing demands on the NHS budgets. NHS Boards across the country are faced with increased waiting times, pressure on recruiting and retaining staff, and difficulty in adopting new technologies and innovative ways of working. It is possible Brexit will impact on NHS budgets and we are concerned how the NHS will cope and adapt in times of increased budget pressures.

18. We would welcome comments from the Scottish Government on how they plan to respond to any financial pressures that may arise post-Brexit.

19. Any reduction in national income could have a disproportionate effect on those living in disadvantaged areas. We have a keen interest in health inequalities and we would be grateful if the Scottish Government could advise what they see as the potential impact of Brexit in relation to this and how they plan to respond to that.

# Reciprocal healthcare

20. Through its membership of the EU, the UK is party to a number of reciprocal healthcare arrangements that apply throughout the EU and the EEA (European Economic Area).

21. We will focus on the main two - the European Health Insurance Card (EHIC) and the S1 scheme.

## European Health Insurance Card (EHIC)

22. The EHIC allows citizens to access healthcare services while visiting any other member state for a period of less than three months. The holder of the EHIC is provided care at either no or low cost, after which the country providing the treatment claims the cost back from the holder's home nation. Around 27 million UK citizens have an EHIC but only approximately 1% of those holding a card make a claim each year, costing the UK £150 million.

23. David Davis MP, Secretary of State for Exiting the European Union, has stated it has been agreed access to the EHIC card will remain post-Brexit. However, if the EHIC or a similar replacement system is not agreed then UK citizens travelling within the EU may need to purchase private health and travel insurance.

24. We heard concerns that should health and travel insurance be required those with existing health conditions such as cancer or kidney disease, who require access to regular treatment, would find it difficult to travel within the EU due to excessive cost or the inability to obtain insurance.

25. The Nuffield Trust noted "The scheme makes it possible for them to travel and be sure that they will be able to access, for example, weekly dialysis abroad when the costs of doing that through private insurance would be prohibitively huge". [3]

26. Community Pharmacy Scotland noted:

> The biggest risk that the Scottish health and social care system faces in this respect is that there is no transitional period or that current EHIC arrangements are not adopted into domestic law in time for March 2019. This would leave Scottish citizens (both with and without existing healthcare conditions) vulnerable when travelling in EEA member states. [4]

## S1 scheme

27. The S1 scheme provides free or low-cost healthcare to citizens receiving a state pension who move to reside in another member state.

28. EU member states claimed £674 million in reciprocal healthcare reimbursement costs from the UK in 2015, whereas the UK claimed £49.7 million in return. It has been suggested this is mainly due to the 190,000 UK pensioners in EEA countries signed up to the S1 arrangements who accounted for £500 million of the claims. The remaining amount related to EHIC reimbursements.

29. The joint EU-UK document on the progress of negotiations has indicated that agreement has been reached on retaining S1 coverage for those already living in other countries on the day of the UK's exit. This means care will continue to be funded by the UK under the S1 scheme for UK pensioners currently living abroad post-Brexit. No agreement has yet been reached for those who wish to move after exit day.

30. The implications of the loss of the S1 scheme could be significant for Scotland. It has been estimated an additional £500 million would be required to care for the people returning to the UK and it has been hypothesised the NHS would need an additional 1,000 hospital beds. [5] This could also have an impact on social care in Scotland with more care home beds required should Scottish citizens return home.

31. The Cabinet Secretary for Health and Sport noted the Scottish Government "recognise that the rights of Scottish citizens to access state-provided healthcare across the EU, and vice versa for EU citizens in Scotland, should be guaranteed after Brexit". [6]

32. The House of Commons Health Committee, in their inquiry report Brexit and health and social care concluded:

> It is in the interest of many hundreds of thousands of British people living across the EU to maintain simple and comprehensive reciprocal healthcare arrangements. The Government's negotiating objective should be preservation of the existing system of reciprocal healthcare so that EU nationals in the UK and people insured by the UK in other EU countries can maintain their access to healthcare.

33. We have concerns about the implications should reciprocal arrangements not continue after the exit date. If Scottish citizens return to the UK as a result of this it would have an impact on health and social care services. We would be grateful if the Scottish Government could advise what work it has undertaken to identify and quantify the risks along with their proposed approach to addressing the potential implications.

34. We believe reciprocal healthcare arrangements must be maintained. The effects on many Scottish citizens either those living elsewhere in the EU or looking to travel could be extremely detrimental if an agreement is not reached.

35. We understand reciprocal arrangements have been a key priority for the Scottish and UK Governments and ask that they continue to prioritise negotiating for the continued use of existing or broadly similar arrangements.

# Public health

36. Many areas of domestic public health law and policy are shaped by membership of the EU with the EU having played an important role in their development. Areas such as tobacco control, clean air and water, safety and quality of donated blood, tissues, cells and organs are all subject to EU regulation.

37. We heard views that offered both positive and negative impacts of Brexit to areas of public health.

38. Chest, Heart and Stroke Scotland noted Brexit may provide an opportunity for Scotland to capitalise on its position as a world leader in public health through accelerating the delivery of public health policies such as banning trans-fat, carcinogenic herbicides and hormone disrupting chemicals. [7]

39. In areas where Scotland has struggled to meet EU directives, the Alliance noted "new and progressive approaches to the realisation of challenging targets related to air and water quality, as well as in relation to agriculture, food and environmental standards, could have benefits for Scotland's public health". [8]

40. BMA Scotland voiced concerns about the possible impact of Brexit. They noted EU legislation has led to significant improvements in the UK's health policy and comment that "Post Brexit it is vital that on both devolved and reserved issues we see a continuing commitment to build on these gains". [9]

## Standards, regulations and trade deals

41. Pan-national approaches to public health are necessary for addressing global health threats. The EU has made environmental factors affecting public health a legislative priority.

42. At present some areas of UK regulation exceed EU minimum requirements and as such Brexit could present an opportunity for the UK to regulate further.

43. Alcohol Focus Scotland noted possible opportunities relating to mandatory alcohol labelling and volume alcohol taxation. [10] Ash Scotland note leaving the EU may make it easier to introduce innovative policies such as minimum tobacco pricing or limits on the amount of tobacco supplied in the UK. [11]

44. However, there have been suggestions new trade agreements, especially those which include investor-state dispute settlement clauses[i], could weaken current safeguards. This mechanism could allow corporations to sue Governments that are

pursuing legislation, potentially in the public health arena, that the corporations believe may interfere with their profits.

45. Ash Scotland noted:

> ...additional rights and freedoms to commercial companies would put real restrictions on the Government's ability to take forward public health policies...negotiations between the European Union and the United States on the transatlantic trade and investment partnership opened up whole new areas of rights for companies to demand access to markets.
>
> Source: Health and Sport Committee 06 March 2018, John Watson, contrib. 32[2]

46. Alcohol Focus Scotland advised the securing of robust exemptions in future trade agreements, which would allow governments to prioritise human health over trade liberalisation, is critical. [12]

47. The Scottish Government confirmed that as well as not wanting to see the Scottish NHS opened up to privatisation through trade deals they also "do not want to see post-Brexit trade deals being allowed to compromise the many public health benefits that we have realised in Scotland, such as in relation to alcohol and tobacco". [13]

48. The Nuffield Trust noted it is possible within international trade deals to limit the sectors or institutions that are covered. This could allow Scottish NHS boards to be excluded from a specific UK trade deal. An element of this is included in the recent Canada-Europe trade agreement. [14]

49. The Scottish NHS is different in many ways to the English NHS. We believe it is vitally important the Scottish NHS is allowed to continue to remain free from privatisation and able to continue pushing forward with public health initiatives.

50. We recommend to all concerned, including the UK Government, that any post-Brexit trade deals should not open up opportunities for privatisation of the Scottish NHS or endanger public health initiatives.

51. Likewise we recommend to all concerned, including the UK Government, that trade deals should not include investor-state dispute settlement clauses applying to the NHS in Scotland.

52. High EU environmental standards in the UK have a positive impact on public health. We encourage the Scottish Government to ensure these continue post-Brexit and would welcome details from the Scottish Government on what steps they are taking to ensure this happens.

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i A procedural mechanism that allows an investor from one country to bring arbitral proceedings directly against the country in which it has invested.

## Surveillance and the European Centre for Disease Protection and Control

53. Cross border threats to public health are monitored by the European Centre for Disease Prevention and Control (ECDC) in Sweden. The ECDC runs systems for the surveillance and early detection of communicable diseases which facilitate prompt sharing of information and expertise when required, for example in relation to pan-European responses to the H1N1 “swine flu” pandemic and efforts to tackle anti-microbial resistance.

54. Only members of the EU and EFTA are members. Norway, Liechtenstein and Iceland participate as EEA/European Free Trade Association countries in several EU agencies, including the ECDC, through agreements that specify financial contributions and roles. However, they are not full member states and do not, therefore, have voting rights or decision-making powers despite their financial contributions.

55. Over and above the ECDC, information on areas such as flu pandemics and swine flu are coordinated by the World Health Organization. The international health regulators, which will remain in place post-Brexit, automatically alert all WHO member countries of any emerging new virus that has the potential to cause a pandemic.

56. Witnesses were agreed Scotland, and the rest of the UK, should aim to continue collaborating and co-operating with the ECDC. Health Protection Scotland noted "The important issues are continuing collaboration and sharing intelligence, data and so on". [15]

57. Community Pharmacy Scotland commented “it is essential that the UK remains a part of this process, or the health of the public will be placed at risk”. [16]

58. Although witnesses believed we should strive to remain part of the ECDC they were optimistic that good practice would continue regardless. The Nuffield Trust advised they were optimistic because good joint working was already in place and it was in everyone's best interests for that to continue. [17]

59. The main concern regarding the possibility of the continued UK membership of the ECDC was whether this could be possible if the UK also left the single market. At present the UK does not appear to be moving towards a deal that would include remaining in the single market or abiding by EU law. As such the EU may not allow the UK to remain a member of the ECDC.

60. We believe it is imperative there is some form of agreement in place to continue to share information and expertise on communicable diseases cross border post-Brexit. The most straightforward option would be to continue as part of the ECDC. However if this is not possible the Scottish and UK Governments must have alternative plans in place.

61. We would welcome details from the Scottish Government of any discussions they have held with the UK Government on how these issues will be dealt with post-

Brexit, including details of any contingency plans should the UK not be allowed to continue as a partner in the ECDC.

# Impact on professionals

62. This section of the report will consider the potential impact of Brexit on the health and social care workforce including the recognition of professional qualifications.

63. Free movement of workers is a fundamental principle of the EU. It entitles EU citizens to live in another EU country, look for a job and work without a permit. One of the most significant potential impacts of Brexit on health and social care relates to workforce. The NHS and social care sector in Scotland currently employ many workers from the EEA, which is made easier by free movement rules arising from EU membership. Free movement of workers is a fundamental principle of the EU.

64. The UK Government has reached a preliminary agreement with the EU on citizens' rights following the UK's withdrawal from the EU. This will allow EU citizens and their families already in the UK, to remain and work in the UK after 29 March 2019. It is expected that this will be extended to residents who are citizens of Norway, Iceland, Liechtenstein and Switzerland.

65. However, uncertainty remains around the potential impact on the retention of staff in the NHS and care services as it is uncertain how many EU citizens will choose to stay post-Brexit.

66. To be able to gauge the potential impact on the NHS and social care services it is imperative to understand the numbers of EEA staff working in these areas. There is little data available on the nationality of NHS and social care workers in Scotland. English data shows that over 62,000 people from non-UK EU countries work in the English NHS, amounting to 5.6% of all staff: almost 10% of doctors and 7% of nurses. Ninety thousand non-UK EU nationals work in adult social care in England (7% of staff). [18]

67. The Scottish Government has estimated there are 12,000 non-UK EU nationals working in health and social care in Scotland (3% of the total health and social care workforce), 4% of nurses and midwives are non-UK EU nationals.

68. Scottish Care advised their data, which came from three pieces of research undertaken in 2017, highlighted that between 6 and 8% of the social care workforce are EEA nationals. This figure goes up to around 8% for nurses who work in the social care sector. [19]

# Recruitment and retention of staff

69. Workforce shortages, already a pressure in some areas of the NHS, may be one of the main health and social care risks of Brexit, as changes to 'free movement of workers' may result in difficulty recruiting and retaining staff.

70. There was consensus of concern across the full range of occupations in the NHS and social care, and across the length and breadth of the country, about the recruitment and retention of staff as a result of Brexit.

71. NHS Highland, who advised they have been successfully promoting opportunities in their health and social care workforce to the migrant community, noted:

> With the uncertainty about the future, we are starting to experience a reduction in the migrant workforce...We have really welcomed the migrant community; they are part of who we are and how we deliver our services in NHS Highland, and we are concerned about what might—or might not—happen.
>
> Source: Health and Sport Committee 06 March 2018, Joanna Macdonald (NHS Highland), contrib. 84[3]

72. BMA Scotland advised should freedom of movement of doctors be withdrawn this will have a major impact on the ability to fill recruitment gaps, with insufficient home-grown doctors available to fill resulting vacancies. [20]

73. The GMC advised:

> The contribution of EEA doctors to the Scottish medical workforce is undoubtedly immense. They comprise 6 per cent of that workforce, but their contribution must not be understood purely on the basis of the raw numbers...this is also about the specialties in which the doctors work. Some of the specialties—for example paediatrics, oncology and radiology—are on the Scottish shortage occupation list.
>
> Source: Health and Sport Committee 06 March 2018, Paul Buckley (General Medical Council), contrib. 86[4]

74. Scottish Care noted "The current recruitment and retention crisis facing social care in Scotland must not be made worse by any system of migration that deters or presents undue barriers and obstacles to those who may wish to come to nurse or care in Scotland". [21]

75. We are as concerned as all our witnesses regarding the future ability of EEA nationals to work and live in Scotland and continue to contribute to the NHS and social care sector.

76. Immigration policy is largely outwith the Scottish Parliament's competence being reserved under Schedule 5 of the Scotland Act 1998. However, the impact of post Brexit immigration law may have an impact on staffing in the NHS and social care in Scotland and one way shortages could potentially be mitigated is through changes to immigration policy.

77. Scotland currently has its own supplementary list within the UK shortage occupation list. The Royal College of Paediatrics and Child Health noted one of the ways to mitigate the impact of Brexit was by "Increasing the number of specialties and roles which are on the Home Office Shortage Occupation List". [22]

78. The BMA advised Scotland already has a degree of separation and the ability to pick and choose which areas it sees as having shortages. The BMA are comfortable with that mechanism and would want to continue with a process that allows Scotland to make sensible decisions on its medical workforce. [23]

79. However, the Scottish Government have contradicted this view and advised the Scottish Shortage Occupation List is not a devolved responsibility –noting they have no formal role in determining what occupations are considered in shortage in Scotland. They advised the Home Secretary makes that decision on the basis of advice from the Migration Advisory Committee (MAC), and the MAC offers that

advice in response to a commission from the Home Secretary. The Scottish Government contributes to this process, but only as a stakeholder and in the same way as any other individual or body can respond to MAC calls for evidence. [24]

80. Another area in which immigration issues arise is around tiered visas. The points-based system for international migration was first introduced in the UK in 2008 and consists of five tiers, each of which can contain multiple categories of visa. Tier 1 is for high value and exceptional talent, including entrepreneurs and investors. Tier 2 is for skilled workers sponsored by an employer. Tier 3 is for low-skilled workers, but has never been implemented. Tier 4 is for students, and Tier 5 is for temporary workers.

81. Current UK Government policy sets limits within visa categories. Under Tier 2 there are 20,700 available each year issued in monthly allocations. If a monthly cap is reached, applications are scored and prioritised based on salary, qualification level and shortage occupation status.

82. Concerns around tier 2 visas were raised with us. The Association of Medical Research Charities noted the cap on the number of tier 2 visas (skilled visa route) has been breached twice in recent months. They saw this as sending a poor message to non-UK EEA citizens and noted "it needs to be changed, and the arbitrary cap needs to be removed". [25]

83. The Scottish Government has previously advised that in December 2017, the cap was reached, and this resulted in the salary threshold for a certificate rising from £20,800 to £55,000. The result of this was many Scottish employers were unable to recruit from overseas, despite otherwise complying with all the rules. [26]

84. We believe there has to be a focus the crucial importance of recruitment beyond the UK has on the safe running of the NHS and social care sector. We believe this needs to be reflected in post-Brexit immigration policy.[ii]

85. We recommend powers to amend the Scottish shortage occupation list, particularly in respect of health and social care occupations, are devolved to the Scottish Government allowing Scotland to make sensible decisions on its medical workforce. They are well placed to understand the current pressures and vacancies within these areas in Scotland and respond accordingly.[iii]

86. We are also concerned around issues with tier 2 visas and the impact caps for the whole of the UK can have on Scotland and call for the Scottish and UK Governments to discuss mechanisms to enable the Scottish Government to approve people wishing to come and work in Scotland who are required to fill positions in essential services.[iv]

87. We recommend the UK Government devolve the necessary powers to determine and vary criteria and thresholds over tier 2 visas to meet Scotland's needs.[v]

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ii Miles Briggs MPS and Brian Whittle MSP dissented from this paragraph.
iii Miles Briggs MPS and Brian Whittle MSP dissented from this paragraph.
iv Miles Briggs MPS and Brian Whittle MSP dissented from this paragraph.

## Research workforce and collaboration

88. Currently, Scotland employs proportionally as a whole more EU (18.3%) and non-EU (13.4%) academic staff compared to the UK. 27% of research-only contracted staff within Scottish higher education are EU nationals.

89. In the research community the overall contribution of EU researchers in medicine, dentistry and health was reported as being 13% of the total. This will include a significant number of clinical, nursing, midwifery, allied health and social care academics, working in the Scottish research community. Many of whom combine research and important clinical work in the NHS. [27]

90. NHS Education for Scotland commented that healthcare science in particular relies on graduates from outside the UK as there are not enough trained at a local level, adding that if Brexit creates any kind of barrier for these candidates joining the NHS in Scotland it will create problems for the scientific workforce. [28]

91. We heard how the vote to leave the EU and the uncertainty are already having an impact on the research workforce. The Association of Medical Charities noted a 2017 survey by the British Heart Foundation showed 80 per cent of the non-UK EU researchers whom it funds are considering moving their careers outside the UK. [29]

92. Cancer Research UK were aware of impacts noting for example if someone graduates from a Paris university and has the choice to go anywhere in the world to work, they are now post-Brexit less inclined to choose the UK . [30] The Royal Society of Edinburgh advised there were already departures from the Scottish workforce. [31]

93. Many witnesses were concerned about the possible impact of Brexit on research collaboration.

94. The Royal Society of Edinburgh advised associate membership of Horizon 2020 is a must, not just for the grants and the activity but for the ability to form networks. Researchers and consumers of research, including the NHS, advised how important those networks are. Most countries do not have the people to build a framework or proper network in areas such as rare disease making the ability to collaborate with other countries essential. [32]

95. The Royal Pharmaceutical Society Scotland noted "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...However, there is already evidence of an increasing reluctance amongst EU collaborators to allow the UK to lead or even be involved in EU projects". [33]

96. The Scottish Government advised they are "keen to see on-going access for Scottish organisations to EU funded research programmes, which will be important to ensure that Scotland can continue to be at the forefront of on-going international research collaboration". [34]

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v Miles Briggs MPS and Brian Whittle MSP dissented from this paragraph.

97. The Association of Medical Research Charities believes we need as few barriers as possible to the movement of scientists and research talent across the UK and Europe.

98. The Royal Society of Edinburgh added "Research, in particular biomedical research that helps patients and changes the way in which we practise medicine, is so important that we could perhaps make an exception and say that free movement of talent, wherever people come from and whether they are younger or older, should be maintained". [35]

99. We believe for the UK, and Scotland in particular, to maintain its global standing, an immigration system designed to enable free movement of the research workforce is essential. Science relies on the flow of ideas and people and cannot be undertaken in isolation. We note the Association of Medical Research Charities that "the UK's future migration system is damaging the UK's reputation and attractiveness as a place to do research". [36]

100. We are concerned that research collaboration is already showing signs of decline. Collaboration is essential not only for high quality research but also the future of patient care. We recommend work is undertaken immediately to show Scotland remains a leader in medical research and remains open for business.

101. We would expect a future immigration system to attract, recruit and retain global scientific talent at all professional levels regardless of nationality.

# Recognition of qualifications, the regulation of professionals and minimum training requirements

102. EU Directive 2005/36/EC (amended by Directive 2013/55/EU ) allows for the recognition of professional qualifications across the EU with the aim of enabling free movement of professionals such as nurses, midwives, doctors, dentists and pharmacists. The relevant sections of these regulations have been incorporated into the Medical Act 1983.

103. The mutual recognition of professional qualifications (MRPQ) was seen as having both advantages and disadvantages by witnesses.

104. BMA Scotland agreed there was a need for MRPQ to continue to facilitate the ongoing exchange of medical expertise across Europe. They noted there is a risk removing automatic recognition would result in an additional barrier for those considering working in the UK. [37]

105. Dr Cornock of the Open University said "If the mutual recognition system is not maintained this is likely to result in delays in recognising an individual health care professionals' qualification". [38]

106. However, the GMC raised some concerns around the current system being too permissive. They noted qualifications in the same specialism around the EU were

not the same. In Southern Europe people training to be a family doctor would not undertake much training in areas such as paediatrics or antenatal or postnatal care all of which are staple elements in primary care in the UK. [39]

107. BMA Scotland pointed out being on a GMC register did not mean someone would automatically qualify for a job. Applicants would still be required to appear before an appointments panel whose job is to ensure that you are able to do the job in front of you, not just that you are able to be registered as a specialist. [40]

108. The GMC also highlighted the difficulty in moving between specialities for medical students observing no allowance was given for the work already undertaken within one speciality. BMA Scotland agreed, noting it was their view "moving between specialties during training should be more straightforward". [41]

109. The Scottish Government wish MRPQ to continue and advised:

> cross-border recognition of professional qualifications, education and training has to continue in order to support that workforce supply pipeline. If it does not, we will have an immediate and serious problem post-Brexit.
>
> Source: Health and Sport Committee 20 March 2018, Shona Robison (Cabinet Secretary for Health and Sport), contrib. 6[5]

110. The GMC also highlighted a potential issue about gathering information on registration and fitness to practice. At present the Internal Market Information (IMI) system is used to transmit and respond to queries about a doctor's registration documents and to send and receive alerts about doctors' fitness to practise. The system warns when a doctor has their practice restricted in any of the EU member states. Post-Brexit there is no guarantee the GMC will still be able to access this.

111. Future decisions on the recognition of professional qualifications will be discussed in the second phase of Brexit negotiations. However we understand it is the UK Government's view mutual recognition of qualifications should continue.

112. Until final decisions on MRPQ are reached by the UK Government and the EU and reflected in a legally binding withdrawal agreement there is great uncertainty about what the future holds. We believe there is a need for the MPRQ to continue post-Brexit. A change to a system similar to that used for those from non-EU countries, would result in delays for professionals gaining entrance to work in the NHS. This could result in consequential delays in treatment for patients.

113. We encourage the Scottish Government to continue to highlight with the UK Government Scotland's desire to continue with MRPQ post-Brexit .

114. In the event that MRPQ does not continue post-Brexit we are interested in hearing about the contingency planning being undertaken in Scotland. We understand the Scottish Government was undertaking various modelling scenarios and it would be useful if the Scottish Government could provide more detail on these and the outcomes they show.

115. We would also welcome information from the Scottish Government on what can be done post-Brexit to make it easier for students to change specialties without

losing credit for work already undertaken. This would benefit both students and the NHS and we are interested in understanding the options available under the current directive and through possible new post-Brexit legislation.

116. It is essential access is still available to the IMI or an alternative system so Scotland and the rest of the UK can check on fitness to practise. We would be grateful if the Scottish Government can advise whether this is expected to continue or what alternative will be in place.

## Planning for Brexit

117. The GMC registration processes and procedures currently accommodate the movement of doctors between the UK and countries inside and outside the EEA. GMC registration with a license to practise allows doctors to practise in all four healthcare systems in the UK.

118. Non-EU medical graduates currently have to take a Professional and Linguistic Assessment Board [42] to be assessed as fit to practise in the UK. Post-Brexit, if medical professionals who qualified in non UK-EEA countries have to be assessed the same way, this could result in delays in recruitment.

119. The GMC noted "If automatic recognition of EEA doctors' training were to cease following exit from the EU, all these doctors would need to apply to us for GP or specialist registration through equivalence routes. It is not difficult to see why this would add to the problems of NHS recruitment.". [43]

120. The Royal Society of Edinburgh agreed:

> For EU nationals, the current process is quick and easy. For people from all over the world outside the European area, it is a long process in which they require hundreds of pages of evidence to say that they are fit to practise in the UK. Although that is important for safety, it would be a big obstacle if it took us a year to get a top researcher into the UK.
>
> Source: Health and Sport Committee 13 March 2018, Professor Dominiczak, contrib. 53[6]

121. We are concerned about the implications for areas of health and social care that the loss of free movement of people could have for areas currently reliant on non UK-EEA staff. It is imperative the UK and Scottish Governments have plans in place to ensure medical and social care staff from the EU are able to work and train in Scotland. If this is not adequately planned for it could have an impact of critical importance for the future of the NHS.

122. Although immigration is currently a reserved matter we believe it is essential the Scottish Government undertake forward planning on how they will deal with some of the issues identified in this part of our report.

123. We would be grateful if the Scottish Government could advise what planning it has undertaken in relation to workforce issues post-Brexit. We would welcome

details of discussions with the GMC and other regulators on how it can be ensured that standards of professional competence can be maintained.

124. We would also welcome details on whether the Scottish and UK Governments have plans for legislative change to improve the current registration system for non-EU nationals. A system that is characterised as being slow, bureaucratic and inordinately burdensome.

# Working time directive

125. In 1993 the Working Time Directive (WTD) was introduced by the EU and has been successfully implemented across the NHS. The directive includes a general limit of 48 hours on the working week. It also sets out the minimum daily and weekly rest breaks. The overriding principle is worker health and safety but this also impacts on patient safety.

126. The WTD will automatically transfer into UK law as part of the Withdrawal Bill. However the WTD is not universally supported and remains a source of controversy within the profession.

127. Prior to the WTD being introduced long on-call hours had been used to combine patient care and learning for junior doctors. This has not been possible since the Directive was implemented and this is the primary criticism of the WTD.

128. Professor Sir John Temple's 2010 report *Time for Training* concluded high quality training could be delivered in 48 hours but traditional models of training and service delivery waste training opportunities and would need to change. The Royal College of Physicians of Edinburgh noted the UK withdrawal from the EU could allow greater flexibility in devising NHS work and training rotas. [44]

129. BMA Scotland however are against any changes to the WTD and raised concerns around the removal and the possible return to 100-hour weeks for junior doctors. They are wedded to the principle of maintaining the regulation of doctors' hours and would continue to stand up strongly for them. [45]

130. The GMC were also against a return to long working hours but believed it may be helpful to look at one or two issues around interpretation as we move forward. [46]

131. Staff and patient safety and high quality care should be at the heart of every service within the NHS and social care and we are concerned about the impact changing the WTD could have.

# Impact on research and clinical trials

132. This section of the report will examine the possible impact of Brexit on research and clinical trials.

## Research funding

133. Funding from the EU has had a significant and positive impact on the quality of health research in Scotland and the rest of the UK. As a global centre of research excellence the UK has been one the largest beneficiaries of EU funding for health research since 2007. The UK also attracts substantially more research funding than it contributes to the EU.

134. The UK Government has stated the UK will be able to participate for the remainder of Horizon 2020 and there is a commitment from the UK Government to underwrite research funding until that time. [47]

135. Non-EU members can participate in Horizon 2020, but post-Brexit, if the UK remained involved it is likely it would have no voting rights although it may be able to influence some decisions through committee work.

136. Witnesses agreed it was essential to have some form of membership of Horizon 2020 and access to future funding programmes like FP9[vi] through associate membership, even though this would not have the same benefits as full membership. The Royal Society of Edinburgh advised "It goes without saying that we need to remain an associated member of horizon 2020 whatever it costs". [48]

137. We also heard optimism from witnesses around future agreements on research funding. The Association of Medical Charities said "It is clear that there is goodwill on both sides of the negotiating table with regard to a future partnership on scientific funding between the UK and the EU". [49]

138. A high-level European Commission group chaired by Pascal Lamy noted in their report *LAB-FAB-APP—Investing in the European future we want: Report of the independent High Level Group on maximising the impact of EU Research & Innovation Programmes* the UK's continued involvement in the programme was a "win-win for the UK and the EU."

139. However, we did hear concerns around the consequences of losing full membership. The main concern was loss of leadership and influence in shaping the strategic direction of research. Dr Flear, Queen's University Belfast, commented that setting the strategic direction of research is incredibly important and loss of influence was a "grave concern". [50]

140. The Royal Society of Edinburgh advised:

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vi The framework programme that will succeed Horizon 2020

> The UK has done very well in leading many of those networks and special interest groups, but we are already seeing a loss of leadership: since the Brexit vote, new groupings and networks that are being created are rarely chaired or co-ordinated by UK researchers.
>
> Source: Health and Sport Committee 13 March 2018, Professor Dominiczak, contrib. 20[7]

141. Cancer Research UK noted the UK Government and, to some extent, the Scottish Government need to be clear on their commitment to funding science and research, display an upward trend and a prioritisation for science and research funding. They believed this would send a global message that the UK is still a home for excellent science. [51]

142. The Scottish Government were clear on the importance of funding, "We are making the case very clearly to Europe that we want to continue to be part of that, and we are showing our goodwill and what we have to offer in research capacity and capability. We keep making the point that we are still open for business in that area and we want to be part of it". [52]

143. We are concerned by the implications on research in Scotland post-Brexit, including the loss of future funding from the successor to Horizon 2020, and the possible loss of Scotland's position at the forefront of research and innovation. However, we are pleased the Scottish Government is pro-actively looking at how the situation can be mitigated and continuing to make the EU aware Scotland remains an integral part of the research landscape.

144. We would encourage the Scottish Government to continue to make this clear to EU partners and the UK Government and to ensure everyone knows Scotland remains a centre for excellence for innovation and research and we would welcome details on any campaign to ensure this is achieved.

# Clinical trials regulation and access

145. Clinical trials concerning pharmaceuticals are subject to the EU Clinical Trials Directive. This directive has been criticised, by some, for being too bureaucratic and is set to be replaced by a new EU regulation coming into force after March 2019. The new regulation is widely seen as an improvement and the UK Government has recently committed to making future clinical trial rules the same as those of the EU.

146. The new regulations harmonise procedures for assessing clinical trial applications, as well as enhancing collaboration between ethics committees, streamlining safety reporting procedures and increasing transparency surrounding the outcomes of clinical trials.

147. The new regulations also create a centralised gateway for clinical trial applications. To be valid all applications will have to be entered into the central database. Even though the UK has committed to implementing this regulation there are concerns the UK would not have access to the database.

148. NHS Research Scotland (NRS) is currently participating in the pilot of the software which will implement the Clinical Trials Regulations across the EU. NRS will be increasing the number of sites involved within Scotland to ensure full and robust feedback, which is intended to help to inform the EU and the UK's stance. [53]

149. Witnesses were unanimous in their belief the UK must continue its alignment with these EU regulations. Dr Flear, Queens University Belfast noted it would be "very wise" and the Royal Society of Edinburgh said "It is absolutely essential that we ensure that happens". [54]

150. The regulations also include a portal and database that will provide important information for researchers helping to ensure patient safety. The Association of Medical Research Charities noted gaining access to these wasn't quite as simple as bringing the text of the regulation into UK law and access post-Brexit would be difficult. [55]

151. Dr Flear advised Article 7 of the European Commission's draft withdrawal agreement states clearly that, upon Brexit, the UK is not to access any EU database, including the clinical trials portal and database. [56]

152. We heard the only way access would be possible is if it was agreed as part of negotiations between the UK and the EU. This could be as part of a comprehensive agreement or as a specific agreement on the clinical trials sector.

153. Community Pharmacy Scotland raised a further concern, "If there is no agreement with the EU, UK patients will not be able to participate in EU trials, which means patients will miss out on the opportunity of potential lifesaving treatments". [57]

154. The Royal Society of Edinburgh felt it would almost be a criminal offence if Scottish patients were excluded from on-going or new trials. [58]

155. The Scottish Government were in agreement with witnesses, advising anything short of access to the EU clinical trials portal will be a disaster and access to it must be secured. They also advised they continue to highlight its crucial importance directly to Europe and the rest of the UK.

156. Continued alignment with the clinical trials regulations is essential as well as continued access to the new portal and database. The possible implications to Scottish patients and research if this is not the case are incalculable.

157. We welcome the work the Scottish Government has already undertaken in this area and the commitment from the UK Government to ensure continued alignment. We urge the Scottish Government to continue working with the EU and the UK Government to ensure access to the portal and database.

158. We also highlight this issue to the UK Government and ask they ensure this is seen as a critical area where agreement must be reached as part of either a comprehensive or specific agreement between the EU and the UK Government.

# Impact on medicines and devices

159. This section of the report will examine the potential impact of Brexit on medicines and medical devices.

## Medicines

160. First we consider the possible impacts of changes to regulation of medicines, access to medicine databases and membership of EURATOM.

### Regulation

161. The system for approval of medicines within the EU is two-fold. The European Medicines Agency (EMA), as a centralised, co-ordinating body, makes an assessment for the European Commission about which medicines should be formally approved. [59] This centralised procedure prevents duplication of spending and work. It also makes the UK and other EU countries a priority for the introduction of new drugs.

162. The Medicines and Healthcare products Regulatory Agency (MHRA) has its own procedures for licensing medicines, which are not covered through the centralised procedure of the EMA. Once a medicine is approved for use by one of these regulatory agencies, the Scottish Medicines Consortium (SMC) assesses how well the medicine works in relation to treatments currently used in the NHS in Scotland and whether they should be funded routinely by domestic health services. [60]

163. Witnesses were very concerned about the prospect of the UK leaving the EMA. Cancer Research UK considers the UK should explore an agreement with the EU to ensure it can continue to take part in the EMA's centralised procedure for drug licensing. They note any future drug licensing system "must not exacerbate delays in access to the most innovative treatments for patients in the UK and across the EU". [61]

164. The Scottish Lifesciences Association saw the current process as frictionless and where concerned that if it becomes encumbered by the need for double testing and double batch release sign-off (where medicines must be approved by two agencies), the supply of drugs to patients will slow down. [62]

165. Witnesses agreed it was essential for the UK to maintain regulatory alignment with the EU and the best option was to remain a member of the EMA in some form. If this was not to happen there could be a range of downsides such as increased costs and the possibility newly licensed medicines would take longer to reach the UK. Under the models currently operated in Switzerland, Canada and Australia new medicines are usually received between 6 and 12 months after countries in the EU. [63]

166. The Royal College of Physicians and Surgeons of Glasgow considered the best possible framework for future regulation lies in ongoing cooperation and partnership between the MHRA and the EMA, as this would provide the best possible

opportunity for patients and clinicians. [64] The Royal Pharmaceutical Society Scotland indicated the UK should "seek to retain its position as an EMA Reference Member State". [65]

167. Another way forward would be through a mutual recognition agreement. This means the recipient state accepts the efficacy of the testing in the originating state and removes the need for double testing. At present any drugs tested in America to Food and Drug Administration standards are tested again when they come to the EU to ensure they accord with European regulations. This is double testing.

168. We understand the EU and the US are currently negotiating a mutual recognition agreement. We would hope for a similar arrangement between the UK and the EU. Community Pharmacy Scotland noted mutual recognition would be very beneficial in order to allow for frictionless trade. [66]

169. The Scottish Lifesciences Association advised after initial clinical studies have been completed, every batch of medicines undergoes continuous safety testing in laboratories. Under EU regulations, testing must take place within EU borders for a drug to be supplied in the EU. [67] For drugs manufacturers in Britain this would mean double safety testing if some sort of mutual recognition was not reached.

170. It is worth noting some witnesses commented that the EU is also dependent on the UK. The Lancet has suggested any separation between the MHRA and the EMA could prove very costly for taxpayers. The EU may need to replace the third of its workforce expertise who are currently British. [68]

171. The Scottish and UK Governments have confirmed they both wish to remain a part of the EMA. The UK Government has confirmed their preferred option is to have associated membership. The Prime Minister stated:

> associate membership of these agencies is the only way to meet our objective of ensuring that these products only need to undergo one series of approvals, in one country
>
> Source: PM speech on our future economic partnership with the European Union

172. The European Council however takes a different view and have advised "the Union will preserve its autonomy as regards its decision-making, which excludes participation of the United Kingdom as a third-country to EU Institutions, agencies or bodies". [69]

173. We are pleased to note the UK Government's intention to seek to maintain regulatory alignment with the EMA. Not only is this in the best interests of the UK but also the best interests of the EU, patients and citizens.

174. We understand this area is still being negotiated and would urge both the Scottish and UK Governments to continue to strongly state the UK's preferred position and to reach agreement with the EU allowing the entire supply chain of pharmaceuticals to continue in a timely fashion. An outcome without regulatory alignment would be unfortunate and costly for all.

175. Whilst the outcome of negotiations remains unknown it is essential the Scottish and UK Governments work on an alternative should negotiations end unfavourably. We would welcome details of the work being undertaken by both governments to ensure we are prepared in the event regulation at a UK level is required.

## Pharmacovigilance

176. Pharmacovigilance is the practice of monitoring the effects of medical drugs after they have been licensed for use, especially in order to identify and evaluate previously unreported adverse reactions.

177. EudraVigilance is the system for managing and analysing information on suspected adverse reactions to medicines which have been authorised or being studied in clinical trials in the EEA. The EMA operates the system on behalf of the EU medicines regulatory network. Once the UK leaves the EU it will not be part of either network.

178. The Royal Pharmaceutical Society Scotland raised questions regarding the impact of sharing pharmacovigilance data and the UK's future relationship with EudraVigilance post-Brexit. [70] Community Pharmacy Scotland noted "From the perspective of ensuring the safety of medicines, we cannot lose access to that level of data". [71]

179. In a submission to the House of Commons Health Committee, Reckitt Benckiser stated

> If the UK was to withdraw from the EudraVigilance pharmacovigilance system, there is not time to build a UK-based system by March 2019, nor would a UK system provide the same level of public safety as it would cover a much smaller population.
>
> Source: Reckitt Nebckiser written submission to House of Commons Health Committee

180. It is our understanding access to EudraVigilance and the pharmacovigilant data can only be maintained post-Brexit if a specific sectoral agreement is reached. Given it would not be possible for the UK to build a new UK-based system by withdrawal date in March 2019 it is essential an agreement is reached.

181. We recommend the Scottish Government encourages the UK Government to seek an agreement that includes mutual recognition of pharmacovigilance studies by the MHRA and the EMA as a priority.

## Medical isotopes and EURATOM

182. The European Atomic Energy Community (EURATOM) regulates the import and export of radioactive and nuclear materials. Importantly this includes medical isotopes used in the treatment of cancer, gamma cameras and PET scans. Radioisotopes are used in around 700,000 diagnostic or therapeutic procedures each year in the UK. [72]

183. These materials cannot currently be produced in the UK, potentially meaning a disruption to the supply of materials required for treating cancer once the UK leaves the EU. It is worth noting that from 2027 the UK will have the ability to produce such isotopes at Hinckley Point Nuclear Power Station.

184. The UK Government announced its intention to leave EURATOM in the explanatory notes which accompanied the EU (Withdrawal) Bill. We understand this is because the legal arrangements of the EU and EURATOM are so intertwined. [73]

185. The Law Society of Scotland commented that “withdrawal from EURATOM raises major concerns of the supply and availability of this lifesaving material”. They go on to state “there is serious concern that the early diagnosis and treatment of cancer would be greatly affected by leaving EURATOM”. [74]

186. Possible delays in trade and customs arrangements were raised as another possible barrier to getting medical isotopes into the country following the withdrawal from EURATOM.

187. The Scottish Lifesciences Association noted:

> One of the issues that we have spotted is nothing to do with medical regulation; rather, it is to do with terms of trade and customs arrangements. If we have customs arrangements that do not allow such products to pass quickly from one country to another, they will degrade and may, in fact, become useless.
>
> Source: Health and Sport Committee 13 March 2018, The Convener, contrib. 126[8]

188. When asked about the Scottish Government's position regarding the possible delay of medical isotopes the Cabinet Secretary for Health and Sport said "We need clarity. We raise the issues and we talk about the impact, which would be an impact across the UK, and not just in Scotland. However, we have yet to get a clear route to resolution". [75]

189. Lord O’Shaughnessy, Parliamentary Under-Secretary for Health in the House of Lords has previously advised the House of Commons Health Committee the UK Government were negotiating a working relationship with the EMA which would replicate the current arrangements on a different legal basis. The negotiations will hopefully result in swift and frictionless customs arrangements allowing medical isotopes to be delivered as quickly as possible. [76]

190. Lord O'Shaughnessy went on to say that currently, 96% of imports outside the EU were cleared by HMRC within seconds, and there is a two-hour clearance commitment for urgent goods.

191. We heard concerns that the withdrawal from EURATOM could result in delays to the UK receiving medical isotopes and as a result, delays in treatment for patients. We understand the EU and EURATOM are legally intertwined. However we believe had the UK wished to remain part of EURATOM some solution, regardless of difficulty, could be found. We would encourage the UK Government to reconsider its decision to leave EURATOM and concentrate on finding a solution to overcome the legal difficulties.

192. We note the UK Government is currently in negotiations with the EU to ensure medical isotopes can be delivered to the UK swiftly and frictionlessly. We welcome these negotiations but are concerned should these be unsuccessful about a back-up plan on how this issue will be dealt with. We would welcome details from the Scottish Government of any contingency plans in place to deal with such an outcome.

# Medical device regulation

193. Medical Devices are regulated in the EU using the CE (European approved) marking scheme which certifies its compliance with EU law. Private and public bodies in member states, including several within the UK, are deemed 'notified bodies' with the right to grant this mark of approval. [77]

194. Under the European Union (Withdrawal) Bill it is accepted that the UK will continue to permit the sale of CE items as this will avoid forcing companies to go through separate regulation processes.

195. One of the main concerns is that medical technology companies currently based in the UK may face an incentive to leave the UK unless UK bodies can become eligible to clear products to be exported across the EU. [78] The turnover of the British medical device technology industry is £17 billion, 6% of the global market, so any losses would have a large impact on the UK economy.

196. In addition, by leaving the EU the UK will no longer have an influence in shaping legislation, policy and regulatory procedures and would be relegated to an observer role.

197. The British Standards Institution notes there are some harmonised standards developed solely to meet European market needs. It goes on to assert it is imperative that the UK does not lose its influence over their development post-Brexit. It considers any loss would "undoubtedly impact business and trade". [79]

198. The Scottish Lifesciences Association advised nearly 50% of the Scottish lifesciences sector is composed of companies in the areas of medical technology and diagnostic testing. They had not heard from a single one of those companies that are even thinking of relocating. They further advised they were unconcerned about companies facing incentives to leave stating its members "are not concerned about the potential threat" [80]

199. We understand at present UK regulatory arrangements for medical devices are completely consistent with EU regulations. We believe they should continue and ensure markets remain intact.

200. The Scottish Government should urge the UK Government to ensure it aligns future regulations with the EU to ensure continued regulatory alignment.

# Common UK frameworks

201. At present all devolved legislation must be compatible with EU law. Membership of the EU ensures legal and regulatory consistency across the UK in these areas. This does not however mean all parts of the UK are identical in these areas. In some cases the EU specifies minimum standards, for instance in relation to aspects of public health. Each country or territory then has discretion, within devolved competences, to determine how to reach the agreed minimum requirements and is free to exceed them.

202. When Brexit occurs the powers exercised at EU level will be repatriated. Many of these powers, for instance those relating to immigration, trade and competition policy are reserved to Westminster.

203. A number of policy areas fall within the legislative competence of the Scottish Parliament. Many of these relate to health and social care such as reciprocal healthcare, tobacco regulation and blood safety. More information can be found in the SPICe briefing Common UK Frameworks after Brexit.

204. The Scottish Government agrees with the UK Government that once the UK leaves the EU there will be a requirement for common UK frameworks in relation to existing EU laws. Consideration should then be given to what powers are included in common frameworks.

205. We were keen to collect views from witnesses on common UK frameworks, in which areas they are desirable and the process under which they should be established. We were interested in what the role of the Scottish Government and the Scottish Parliament should be, in the development of common frameworks, to safeguard the interests of patients and research in Scotland.

206. NHS Orkney believes common framework arrangements could limit the extent to which the Scottish Parliament can tailor legislation to meet Scotland's specific requirements, particularly if the frameworks are developed via legislation at Westminster rather than as intergovernmental agreements. [81]

207. Scottish Care noted Scotland has developed a health and social care system that is legislatively based on human rights principles. They raised concerns the UK Government may wish to remove the protections and safeguards within human rights legislation. This includes the possible effect on Scottish legislation around adult support and protection, adults with incapacity, and mental health care and treatment—all coherently based on the ECHR and the Human Rights Act 1998. [82]

208. In general the distinct health policy in Scotland was referenced by witnesses and the need for this to continue was raised. NHS Highland noted "The governance that we have in Scotland, particularly around social care service delivery, is unique in the UK... we want to ensure that any framework builds on what we already have and the uniqueness that exists in Scotland". [83]

209. Royal Blind advised it was "imperative a distinct approach to the delivery of health services in Scotland is maintained and the frameworks ensure policies can be designed to address the specific needs of each territory". [84]

210. The Royal College of Physicians and Surgeons of Glasgow agreed any future changes in common frameworks should respect the Scottish devolution settlement. They should also protect the current responsibilities that the Scottish Parliament has to legislate for the health and social care sector in Scotland. [85]

211. In certain areas, such as human tissue regulation, we heard agreement on the need to make decisions at a UK level. The Nuffield Trust noted the European Union's harmonisation of how things such as blood and organs are dealt with has facilitated, to some extent, "those who move across borders within the EU to address pressing medical needs". They went on to say "it would be a great shame to lose that harmonisation with the rest of the EU but, if we do, I certainly would not want to lose at least the ability to move organs between Scotland, England and Wales". [86]

212. Areas around public health were ones where witnesses felt Scotland should continue to be able to make their own decisions and concerns were raised that public health initiatives could be stifled if that was not the case.

213. Cancer Research noted there is a “clear role for the Scottish Government in safeguarding the interests of patients and research in Scotland." [87] ASH Scotland advised in relation to tobacco regulations that it is important to maintain the flexibility and innovation that have come from different areas. [88]

214. Cancer Research suggested the benefits for patients would by greater if this committee, along with the Scottish Parliament and the Scottish Government, has a voice in championing a UK approach that involves harmonisation with the EU. [89]

215. In relation to research and clinical trials witnesses were very clear the UK, and Scotland, should not diverge from the EU. The Royal Society of Edinburgh noted the continued need for a "harmonised approach". [90]

216. Reciprocal healthcare was highlighted by Community Pharmacy Scotland as an area where it would be inappropriate for a common framework following Brexit. They advised "whilst any arrangement would likely mirror Westminster's initially, the devolved nations must have the freedom to pursue relationships with individual countries independent of one another". [91]

217. The distinct public health policy environment in Scotland was referenced on numerous occasions. This highlights an area where it is essential the Scottish Parliament continues to retain its ability to agree and set its own policy. Scotland currently exceeds targets in many areas and continues to push forward innovative policies. The Scottish Parliament's ability to take decisions in the best interests of Scotland must not be diluted.

218. It is essential public health powers be devolved to Scotland and not retained at UK level. Scotland has proceeded with many public health initiatives ahead of the rest of the UK and the devolution of repatriated policy areas will continue to allow the Scottish Parliament and the Scottish Government to take decisions in the best interests of Scotland.

219. There are areas where it makes sense for UK wide common frameworks to exist. These include blood safety, data protection, organs and tissue. It is desirable UK frameworks mirror those of the EU as closely as possible. It would be in no-one's interests for these to diverge in Scotland.

220. We agree with the Finance and Constitution Committee[vii] that this process is not solely a matter for Governments but must be transparent and inclusive. The Scottish Government and the Scottish Parliament have a strong history of engagement with organisations and the general public. This will continue to be required for powers devolved from the EU and it is essential the Scottish Parliament has a role in scrutinising proposed common frameworks to safeguard the interests of patients, staff and stakeholders across Scotland. This Committee must have the opportunity to consider each of the common frameworks in relation to health and social care negotiated at governmental level before they are finalised.

vii Finance and Constitution Committee, European Union (Withdrawal) Bill LCM - Interim Report (Para 100)

# Conclusions

221. Access to free healthcare at the point of need is a founding principle of the NHS and it is essential that principle must be upheld. It is apparent how much of our health and social care system is intertwined with areas of EU regulation and that without EU workers, from carers to consultants, the NHS and social care services in Scotland which are already stretched, would be placed under extreme pressure.

222. It is essential patients continue to have timely and up to date access to the latest medical and social care. There are risks that treatments could be compromised or delayed in Scotland post-Brexit. It is imperative the Scottish and UK Governments continue to negotiate with the EU to ensure the concerns we highlight in this report do not become a reality for people in Scotland and the rest of the UK.

223. On the domestic front we have made a number of recommendations about areas directly affecting Scotland. We want negotiations between the Scottish and UK Governments to move quickly and for common UK frameworks that are both transparent and inclusive to be agreed in early course allowing all stakeholders maximum opportunity to prepare. One of the founding principles of the Scottish Parliament is openness and encouraging of participation and this will be required through the scrutiny of common UK frameworks in relation to health and social care. This must include (before agreements are reached) a central scrutiny role for the Scottish Parliament, and this Committee, along with opportunities for input from the people of Scotland.

# Annexe A - Minutes of meeting

28th Meeting, 2017 (Session 5) Tuesday 28 November 2017

**8. Impact of leaving the European Union on health and sport in Scotland (in private):** The Committee considered and agreed its approach to its inquiry.

8th Meeting, 2018 (Session 5) Tuesday 6 March 2018

**2. Impact of leaving the European Union on health and social care in Scotland:** The Committee took evidence from—

- Mark Dayan, Policy Analyst, Nuffield Trust;
- Dr Syed Ahmed, Clinical Director, Health Protection Scotland;
- John Watson, Deputy Chief Executive, ASH Scotland;

and then from—

- Dr Donald Macaskill, Chief Executive Officer, Scottish Care;
- Joanna Macdonald, Director of Adult Social Care, NHS Highland;
- Dr Peter Bennie, Chair, BMA Scotland;
- Paul Buckley, Director of Strategy and Policy, General Medical Council.

**3. Impact of leaving the European Union on health and social care in Scotland (in private):** The Committee considered the evidence heard earlier in the session.

9th Meeting, 2018 (Session 5) Tuesday 13 March 2018

**1. Impact of leaving the European Union on health and social care in Scotland:** The Committee took evidence from—

- Dr Mark Flear, Senior Lecturer in Law, School of Law, Queen's University Belfast;
- Dr Cat Ball, Policy Manager, Association of Medical Research Charities;
- Gregor McNie, Head of External Affairs, Devolved Nations, Cancer Research UK;
- Professor Dame Anna Dominiczak, Vice-Principal and Head of College of Medical, Veterinary and Life Sciences, University of Glasgow, representing The Royal Society of Edinburgh;

and then from—

- Michael Clancy, Director of Law Reform, Law Society of Scotland;
- Matt Barclay, Director of Operations, Community Pharmacy Scotland;
- John Brown, Director of Policy, Scottish Lifesciences Association.

**7. Impact of leaving the European Union on health and social care in Scotland (in private):** The Committee considered the evidence heard earlier in the session.

10th Meeting, 2018 (Session 5) Tuesday 20 March 2018

**2. Impact of leaving the European Union on health and social care:** The Committee took evidence from—

- Shona Robison, Cabinet Secretary for Health and Sport, and
- Shirley Rogers, Director of Health Workforce and Strategic Change, Scottish Government.

**3. Impact of leaving the European Union on health and social care (in private):** The Committee considered the evidence heard earlier in the session and agreed to produce a report with its recommendations.

# Annexe B - Evidence

## Written evidence

- BREX001 Community Pharmacy Scotland
- BREX002 Royal College of Physicians of Edinburgh
- BREX003 Scottish Social Services Council
- BREX004 Camphill Scotland - combined subs
- BREX005 Care Inspectorate
- BREX006 Healthcare Improvement Scotland
- BREX007 NHS Education for Scotland
- BREX008 NHS Orkney
- BREX009 Royal Blind
- BREX010 the ALLIANCE
- BREX011 Royal College of Psychiatrists in Scotland
- BREX012 ASH Scotland
- BREX013 NHS National Services Scotland
- BREX014 Who Cares? Scotland
- BREX015 GMC
- BREX016 Scottish Independent Advocacy Alliance
- BREX017 British Dental Association Scotland
- BREX018 Royal College of Pathologists
- BREX019 Cancer Research UK
- BREX020 Scottish Womens Convention
- BREX021 UNISON Scotland
- BREX022 Association of Medical Research Charities
- BREX023 National Pharmacy Association
- BREX024 Royal College of Physicians and Surgeons of Glasgow
- BREX025 Scottish Association of Social Work

- BREX026 RCGP Scotland
- BREX027 The Royal College of Paediatrics & Child Health Scotland
- BREX028 RCN Scotland
- BREX029 Chest Heart & Stroke Scotland
- BREX030 Alcohol Focus Scotland
- BREX031 Scottish Care
- BREX032 British Standards Institution
- BREX033 General Dental Council
- BREX034 Law Society of Scotland
- BREX035 Parkinson's UK in Scotland
- BREX036 Scottish Partnership for Palliative Care
- BREX037 NHS Health Scotland
- BREX038 Royal Pharmaceutical Society Scotland
- BREX039 BMA Scotland
- BREX040 The Royal Society of Edinburgh
- BREX041 COSLA
- BREX042 Dr Marc Cornock, The Open University

On 24 January 2018 the Cabinet Secretary for Health and Sport provided a response to the Committee's call for views:

- Letter to the Convener from the Cabinet Secretary for Health and Sport

# Official reports

- Tuesday 6 March 2018 - evidence from stakeholders
- Tuesday 13 March 2018 - evidence from stakeholders
- Tuesday 20 March 2018 - evidence from the Scottish Government

[1] Health and Sport Committee 06 March 2018, Mark Dayan (Nuffield Trust), contrib. 4, http://www.scottish.parliament.uk/parliamentarybusiness/report.aspx?r=11408&c=2071315

[2] Health and Sport Committee 06 March 2018, John Watson, contrib. 32, http://www.scottish.parliament.uk/parliamentarybusiness/report.aspx?r=11408&c=2071343

[3] Health and Sport Committee 06 March 2018, Joanna Macdonald (NHS Highland), contrib. 84, http://www.scottish.parliament.uk/parliamentarybusiness/report.aspx?r=11408&c=2071395

[4] Health and Sport Committee 06 March 2018, Paul Buckley (General Medical Council), contrib. 86, http://www.scottish.parliament.uk/parliamentarybusiness/report.aspx?r=11408&c=2071397

[5] Health and Sport Committee 20 March 2018, Shona Robison (Cabinet Secretary for Health and Sport), contrib. 6, http://www.scottish.parliament.uk/parliamentarybusiness/report.aspx?r=11437&c=2077280

[6] Health and Sport Committee 13 March 2018, Professor Dominiczak, contrib. 53, http://www.scottish.parliament.uk/parliamentarybusiness/report.aspx?r=11429&c=2075637

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1 Who Cares? Scotland written submission

2 BMA Scotland written submission

3 Health and Sport Committee Official Report 6 Mar 2018 COL 4

4 Community Pharmacy Scotland written submission

5 Health and Sport Committee Official Report 6 Mar 2018 COL 4

6 Health and Sport Committee Official Report 20 Mar 2018 COL 5

7 Chest, Heart and Stroke Scotland written submission

8 The ALLIANCE written submission

9 BMA Scotland written submission

10 Alcohol Focus Scotland written submission

11 ASH Scotland written submission

12 Alcohol Focus Scotland written submission

13 Health and Sport Committee Official Report 20 Mar COL 6

14 Health and Sport Committee Official Report 6 Mar 2018 COL 11

15 Health and Sport Committee Official Report 6 Mar 2018 COL 15

16 Community Pharmacy Scotland written submission

17 Health and Sport Committee Official Report 6 Mar 2018 COL 16

18 House of Commons Health and Social Care Committee - Brexit and health and social care inquiry

19 Scottish Care written submission

20 Health and Sport Committee Official Report 6 Mar 2018 COL 24

21 Scottish Care written submission

22 The Royal College of Paediatrics and Child Health written submission

23 Health and Sport Committee Official Report 6 Mar 2018 COL 25

24 Scotland’s population needs and migration policy: Discussion paper on evidence, policy and powers for the Scottish Parliament

25 Health and Sport Committee Official Report 13 Mar 2018 COL 15

26 Scotland’s population needs and migration policy: Discussion paper on evidence, policy and powers for the Scottish Parliament

27 The Royal Society of Edinburgh written submission

28 NHS Education for Scotland written submission

29 Health and Sport Committee Official Report 13 Mar 2018 COL 8

30 Health and Sport Committee Official Report 13 Mar 2018 COL 8

31 Health and Sport Committee Official Report 13 Mar 2018 COL 8

32 Health and Sport Committee Official Report 13 Mar 2018 COL 5

33 The Royal Pharmaceutical Society written submission

34 Health and Sport Committee Official Report 20 Mar 2018 COL 6

35 Health and Sport Committee Official Report 13 Mar 2018 COL 14

36 Association of Medical Research Charities written submission

37 BMA Scotland written submission

38 Dr Marc Cornock, Open University written submission

39 Health and Sport Committee Official Report 6 Mar 2018 COL 32

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41 Health and Sport Committee Official Report 6 Mar 2018 COL 33

42 gmc-uk.org/registration-and-licensing/join-the-register/plab

43 GMC written submission

44 The Royal College of Physicians of Edinburgh written submission

45 Health and Sport Committee Official report 6 Mar 2018 COL 37

46 Health and Sport Committee Official report 6 Mar 2018 COL 38

47 UK participation in Horizon 2020: UK government overview

48 Health and Sport Committee Official Report 13 Mar 2018 COL 5

49 Health and Sport Committee Official Report 13 Mar 2018 COL 5

50 Health and Sport Committee Official Report 13 Mar 2018 COL 7

51 Health and Sport Committee Official Report 13 Mar 2018 COL 8

52 Health and Sport Committee Official Report 20 Mar 2018 COL 13

53 Letter from the Cabinet Secretary of Health and Sport to the Convener

54 Health and Sport Committee Official Report 13 Mar 2018 COL 20-21

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59 European Medicines Agency. (2017). What we do - authorisation of medicines

60 Law Society of Scotland. (2017). Analysis Paper: The UK withdrawal from the EU and the potential impact on health related matters

61 Cancer Research UK written submission

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65 The Royal Pharmaceutical Society Scotland written submission

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69 Council of the European Union - European Council (Art.50) (23 March 2018) - Draft guidelines

70 The Royal Pharmaceutical Society Scotland written submission

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72 Parliamentary Office of Science and Technology, POSTNOTE: Supply of Medical Radioisotopes, Number 558 July 2017

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74 The Law Society of Scotland written submission

75 Health and Sport Committee Official Report 20 Mar 2018 COL 27

76 House of Commons Health Committee Oral evidence: Brexit – medicines, medical devices and substances of human origin

77 How will our future relationship with the EU shape the NHS?

78 Leaving the EU - Implications for Health and Social Care

79 The British Standards Institution written submission

80 Health and Sport Committee Official Report 13 Mar 2018 COL 34

81 NHS Orkney written submission

82 Health and Sport Committee Official Report 6 Mar 2018 COL 39

83 Health and Sport Committee Official Report 6 Mar 2018 COL 40

84 Royal Blind written submission

85 The Royal College of Physicians and Surgeons of Glasgow written submission

86 Health and Sport Committee Official Report 6 Mar 2018 COL 9

87 Cancer Research UK written submission

88 Health and Sport Committee Official Report 6 Mar 2018 COL 18

89 Health and Sport Committee Official Report 6 Mar 2018 COL 4

90 Health and Sport Committee Official Report 6 Mar 2018 COL 2

91 Community Pharmacy Scotland written submission