Document 1 – Extract from email chain on European Centre for Disease Prevention and Control

Email 1

I have been speaking with colleagues in DH, trying to disentangle a bit further the potential impacts of Brexit on health protection.

On ECDC, I think our shared view is that the UK would still want to be a member, and this looks like something which wouldn't be legally problematic. We will wait and see what approach comes out in negotiations about how much we're charged to be involved in EU agencies.

Another area is around European surveillance, and there's also a potential cost pressure here. However, I just wanted to check at a practical level if HPS are currently involved in European meetings on use and interpretation of surveillance data? Currently UK representatives have their travel costs refunded by the Commission, but I'm not sure if this is something HPS are involved in.

Email 2

I have been giving some thought at HPS and asked various consultant and topic lead colleagues on the possible impact of Brexit and I must admit I got very little from them.

As you will be fully aware, it is PHE that is the focal point in the UK for ECDC liaison and as a consequence the majority of our collaboration with the ECDC is done through PHE rather than directly with a few exception mainly in the area of flu. Some activities that we undertake directly with ECDC include [redacted] attending ECDC sponsored and funded EPIET training meetings and EPIET trainee supervisors meetings as we have had two such trainees in recent years. [redacted] also attends various flu and flu vaccine related annual meetings to present Scottish data along with colleagues from PHE as Scotland contributes significantly to flu swabbing surveillance disproportionate to our population size.

We obviously provide a lot of surveillance data to ECDC as required by EU mandates and in return we get summary reports on EU surveillance. Apart from [redacted], other consultants and topic leads do not travel

much to ECDC offices but collaborate through PHE who attends various ECDC meetings representing all the UK countries.

In Summary my assessment is that the health protection surveillance and service delivery system in the UK countries are much better developed than other parts of Europe and on the whole we gain less from the EU on this area than the EU gets from the UK. We do get various alerts and risk assessment from the ECDC on various emerging public health threats but often we do our own risk assessment in the UK anyway.

So other than potential loss of collaboration with EU colleagues on research with some modest funding, not able to access EPIET training and use some of the ECDC standards/guidelines as a benchmark, I really don't anticipate much impact on the UK if we cannot continue with on-going collaboration.

In Summary my assessment is that the health protection surveillance and service delivery system in the UK countries are much better developed than other parts of Europe and on the whole we gain less from the EU on this area than the EU gets from the UK. We do get various alerts and risk assessment from the ECDC on various emerging public health threats but often we do our own risk assessment in the UK anyway.

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Document 2 - Extract from responses to House of Commons inquiry - blood tissues and organs

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

We would anticipate fairly limited direct impacts on substances of human origin for Scotland. One of the main concerns, along with other parts of the NHS, will be to avoid any impact on the workforce, given the need to retain and continue to attract e.g. transplant surgeons from other EU member states. We would hope to continue a similar regulatory approach under the Medicines and Healthcare products Regulatory Agency (MHRA) and the Human Tissue Authority (HTA) post-Brexit. We will want those Regulations which implement EU safety and procedural measures under the Blood, Tissues and Cells and Organ Directives to keep pace with any changes made in future at EU level (whether it is ultimately agreed that this is done via UK-wide or Scottish regulations) in order to allow for continued free movement of organs, blood, tissues and cells from EU and EEA member states where needed.

For the Scottish National Blood Transfusion Service (SNBTS), there is a risk of loss of membership of the European Blood Alliance, with access to shared expertise and experience, standards, benchmarking, common procurement, etc. There is also the potential for loss of early visibility on emerging infectious diseases provided through the European Centre for Disease Prevention and Control (ECDC).

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

The Scottish Government would be keen to see ongoing access for UK/Scottish organisations to EU-funded research programmes. This will be important to ensure that Scotland and the rest of the UK can continue to be at the forefront of ongoing research collaboration in important areas, such as developing regenerative medicine techniques. Loss of access to EU funding, such as Horizon 2020, will significantly impact on research in Scotland, unless mitigated. It is likely that international companies will be more likely to invest in facilities, including manufacturing, within the EU which is a significantly bigger market than the UK, rather than risk tariffs and other barriers to trade. For similar reasons, international pharmaceutical companies may choose to carry out clinical trials and obtain marketing authorisation in the EU first, rather than the UK, leading to delayed access to new medicines.

Finally, highly specialised research talent is internationally mobile. Barriers to immigration are likely to impede the recruitment of the best scientists and clinicians to UK and Scottish life sciences and thereby undermine our competitiveness.

Document 3 - Extract from EU Dentist's Network - Note from First Meeting

The key points raised at the event were:

* There was a feeling that until relatively recently, many dentists from EU countries were interested in working in Scotland, however observations were made that currently it is less attractive. It was felt that there were a number of reasons for this; the economic situation in many European countries improving, lower tax rates on income in European countries, the value of the pound decreasing, and a perception that there was a fear of being complained about to the regulatory body (the General Dental Council) either by the patient or health service and the consequences of this.
* Closely linked to this were views that recruiting dentists from the EU had become increasingly difficult. With one participant commenting that he had seen a reduction in the number of applications from EU nationals to work in their practices.
* Many participants were not concerned about the impact of Brexit on their personal circumstances with one saying that they "don't see it being uncertain". There was, however comments made that their fellow dentists who had partners who didn't work in health care were more concerned.

Document 4 - Extract from EU Dentists Network - Note from Event

Key Points Raised - Brexit

- Some participants said that as EU nationals owning their own homes in Scotland they felt concerned that they may experience prejudice in the future when buying or selling property.
- The economic situation in Aberdeen was discussed with some commenting that their spouses work in different sectors out-with health and were worried about their status following Brexit.
- The administrative processes for residency cards are time consuming, one participant reported that the Home Office were sending back photos they believed were out of date.
- In relation to applying for citizenship, participants reported confusion from their family members and friends on whether they needed to apply for citizenship. They asked for clarity.
- Questions were asked about the future of university tuition fees after Brexit. Will non UK EU students still be eligible for free tuition?
- Participants raised questions about whether qualifications from EU countries would still be recognised after Brexit.
- Concern was raised about their children being able to study in Scotland.
- Serious concerns about the value of the pound. The value of the pound after Brexit will have an impact on their businesses and this may lead to EU dentists choosing other countries to work in.
- One participant reported that she had heard that should an EU national leave the UK for a short period of time after Brexit, they would be asked whether they had health insurance on their return to a UK airport. Whilst the participant recognised that this may not be the case, she requested clarification.
- Closely linked to this were questions about the European Health Insurance Card (EHIC) and whether cards would be valid after Brexit.
- Questions were raised about pension arrangements after Brexit, would EU nationals still be eligible to receive their pension in Scotland? Would they still be able to transfer pension contributions to and from the UK pension systems?

Document 5 - Extract from Email - Euratom - medical radioisotopes

- The 'timely access' is due to being a member of Euratom and consequently of the Euratom Supply Agency (ESA) which in part deals with the acquisition and distribution of medical isotopes across the EU
- Although an affiliation/association/alignment may see us have access to certain areas of the Treaty, the most probable outcome is one where we lose access to the ESA altogether and fundamentally that potentially leads to two further consequences:
    - The UKG must renegotiate an agreement with the EU for acquiring medical isotopes plus transport arrangements
        - Currently there are no customs duties applied and no delay for import/export procedures. This will become a customs arrangement related issue. Increased time to cross-borders and increased cost likely
    - The UKG could negotiate access to medical isotopes outside of the EU although the time taken for transport would be greater but this was the situation when accessing material from Canadian reactors

The grey area here has been with the loss of supply and the need to renegotiate that supply. Naturally because of the high importance of their use, they cannot have a gap in supply. Leaving Euratom does not however stop us in any way from being able to 'source' medical isotopes, it simply stops the continuity of supply from our existing arrangements under Euratom and the arrangements that govern their transport.

Document 6 – Euratom

Nuclear Safeguards Bill Fact Sheet – Medical Radioisotopes [1]

Does leaving Euratom affect our ability to import medical radioisotopes?

The Euratom Treaty refers to medical radioisotopes in the context of promoting research (Annex I of the Treaty) and prohibition of customs duties and quantitative restrictions on imports and exports between EU Member States (Annex IV). These references do not set any restrictions or limitations on trade in such materials with countries outside the EU. Hence there is nothing in the Euratom Treaty impeding the UK's ability to continue to access medical radioisotopes from the EU when the UK is no longer a Member State. The UK's ability to import medical radioisotopes from Europe and the rest of the world will not be affected by our withdrawal from Euratom.

Regulatory framework and customs arrangements

At present, Euratom have put in place notification requirements [2] that apply to shipments of sealed sources, and other relevant sources, between Euratom Member States to inform authorities that these goods are being transported. The EU Withdrawal Bill will convert any relevant and directly applicable laws into domestic legislation, outside Euratom. This will ensure the UK exits the EU and Euratom with certainty and control. There are currently no customs duties or restrictions on movement of goods such as medical radioisotopes between the UK and other EU Member States as we are all part of the EU Single Market. When we leave the EU, the UK Government will have control over what customs arrangements will be in place at the UK border. It is in the interest of both the UK and EU to avoid disruption in the timely access of treatment to patients; and to ensure that cross-border trade, especially on medical products such as medical radioisotopes, is frictionless as possible. This will be part of the broader negotiations of the UK's future relationship with the EU.

[1] Nuclear Safeguards Bill Fact Sheet – Medical Radioisotopes, Department for Business, Energy and Industrial Strategy (DBEIS);

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/673062/Nuclear_Safeguards_Bill_Factsheet_-_Medical_Radioisotopes.pdf)

[2] Council Regulation 1493/93/Euratom on shipment of radioactive substances between Member States

http://eurlex.europa.eu/legalcontent/EN/ALL/?uri=celex:31993R1493

First quarterly update to Parliament on the Government's progress on the UK's exit from the Euratom Treaty, Department for Business, Energy and Industrial Strategy (DBEIS) [3]

Wider Issues

Lastly, the supply of medical radioisotopes has been raised as a concern by Parliament and stakeholders. We have made clear that our withdrawal from Euratom, including direct involvement in the European Observatory on the supply of medical radioisotopes, will not affect our ability to import medical radioisotopes. Nevertheless, as stated in the Written Ministerial Statement of 11 January 2018, the Government will be seeking a close and effective future association with Euratom. The precise nature of this association including discussions with the EU and Member States on how best to continue cooperation in the work of the European Observatory, remains subject to future negotiations.

[3] Quarterly update to Parliament on the Government's progress on the UK's exit from the Euratom Treaty, Department for Business, Energy and Industrial Strategy (DBEIS);

https://www.gov.uk/government/publications/euratom-exit-quarterly-update-january-to-march-2018

Written ministerial statement made in January 2018 by Greg Clark, Secretary of State for Business, Energy and Industrial Strategy[4]

'...the Government's strategy is twofold: through negotiations with the European Commission we will seek a close association with Euratom and to include Euratom in any implementation period negotiated as part of our wider exit discussions; and at the same time, to put into place all the necessary measures to ensure that the UK could operate as an independent and responsible nuclear state from day one.'

'...to seek continuity of ***open trade arrangements*** *for nuclear goods and products to ensure the nuclear industry is able to continue to trade across EU borders without disruption'*

[4] Written ministerial statement made in January 2018 by Greg Clark, Secretary of State for Business, Energy and Industrial Strategy (BEIS);

https://www.parliament.uk/business/publications/written-questions-answers-statements/written-statement/Commons/2018-01-11/HCWS399/

British Medical Association (BMA) Brexit Briefing on Euratom[5]

Key Points

Euratom facilitates a secure and consistent supply of radioisotopes which have a range of applications in medicine. They are vital for diagnosing particular

diseases through nuclear medicine imaging techniques, treatment of cancer through radiotherapy, as well as palliative relief of pain, and biochemical analysis in clinical pathology.

Working outside of Euratom would:

- reduce the reliability by which the UK can obtain these vital supplies, leave the UK increasingly exposed to supply chain risks, and restrict the ability of the EU (European Union) and UK to share expertise; and
- weaken collaborative links between the UK and EU on nuclear-medicine research.

To ensure the supply of nuclear materials and promote nuclear medicine research, the UK Government should negotiate a formal agreement with Euratom, similar to ones in place with other non-EU countries such as Switzerland.

Should there be a failure to agree a withdrawal agreement by March 2019, the UK would have to operate outside of Euratom and source radioisotopes from outside of this framework. This would remove the guarantee of consistent and timely access to radioisotopes, potentially resulting in delays in diagnosis and cancelled operations for patients. In the longer term, it would also restrict the ability of the UK and EU to benefit from sharing expertise in radiation research, radiation protection and the disposal of radioactive waste.

[5] British Medical Association (BMA) Brexit Briefing on Euratom;

https://www.bma.org.uk/collective-voice/influence/europe/brexit/bma-brexit-briefings/euratom

Press release - British Nuclear Medicine Society (BNMS) statement on leaving Euratom[6]

The BNMS has carried out extensive work on the future supply of medical radioisotopes in the UK. We share the view of the Royal College of Radiologists (RCR) that leaving Euratom will impact on the supply and cost of medical radioisotopes and would like to see greater clarity regarding the future arrangements. We are working with NHS England on the security of the future supply chain for medical radioisotopes to UK hospitals.

Any confusion regarding the regulatory aspects related to safe provision and transport of radioactive medicinal products between Great Britain and Europe should be dispelled as soon as possible.

[6] Press release - British Nuclear Medicine Society (BNMS) statement on leaving Euratom;

https://www.bnms.org.uk/news/press-release-british-nuclear-medicine-society-statement-on-leaving-euratom.html

Euratom submission to Roseanna Cunningham MSP, Cabinet Secretary for the Environment, Climate Change and Land Reform from Charles Stewart-Roper

The UK does not have a current capacity for production of either uranium ores or medical radioisotopes, with no current plan for this to change in the future. Naturally this means that any future situation which does not involve a relationship with Euratom would severely impact the UK's ability to retain continuity of supply of medical radioisotopes.

Although medical isotopes aren't classed as special fissile material and are therefore not subject to safeguards, they are included under Chapter 9 and Annex IV relating to customs duties, under lists A^2 and B. It is also interesting to note that the UK currently imports 50% of its supply of medical radioisotopes from outside the EU (South Africa) and 50% from within; 35% from the Netherlands and 15% from France. UKG have so far stated that leaving Euratom will not impact the availability of medical radioisotopes, however this will not be the case as leaving Euratom might lead to added customs duties on all imports/exports of nuclear material, including medical radioisotopes, making it more expensive and more difficult for the UK to secure supply. There is also a clear difference between retaining the ability to import isotopes and being part of an organisation that has a purpose to.
We should seek an outcome for Scotland which does not see the interruption of supply of nuclear materials for civil nuclear, including power and non-power related activities. This is inclusive of medical radioisotopes.

Assessment report on the impacts of Euratom withdrawal, Radioactive Waste and Decommissioning Policy Team

The demonstrable issue for the UK on withdrawal from Euratom is the loss of supply contracts for nuclear power related material, such as ores and fuel. The UK does not have any proven Uranium reserves for exploration through mining and also does not have the production capacity for medical radioisotopes, with no current plans to change this in the future.

Although the UK's ability to access isotopes will not be affected by withdrawal, the issue relates to the classification of the material under Chapter 9 and Annex IV and hence the applied customs duties on all imports/exports and the length of time taken for the delivery of material with extended customs procedures on import likely. Development of NCAs with countries outside of the EU should be a more attractive solution to supply medical radioisotopes and nuclear fuel, with the IAEA NFA acting as a back-up if they can be negotiated.

Document 7 - Extract from EU Withdrawal Brief

Lines to take

- The Scottish Government believes that Brexit represents a significant threat to the UK's and, in particular, to Scotland's future economic and social prosperity. At present, considerable, and damaging, uncertainty characterises both the negotiations and the UK Government's ultimate objectives with regard to the future relationship with the EU.

- As the Cabinet Secretary for Health and Sport made clear during her appearance at the Scottish Parliament's Health and Sport Committee inquiry into Brexit on 20 March 2018, Brexit could have significant impacts on the health and social care sector in Scotland.

- For example, if free movement of EU nationals in the UK is curtailed as a result of the Brexit negotiations, this could have potentially serious consequences for the recruitment and retention of health and social care workers in Scotland. It could also negatively impact the free movement of medical researchers between Scotland and other EU countries and it could affect the ability of our academic institutions to attract medical students to come here to study and train, impacting on the provision of health care.

- The Scottish Government believes that Scotland's health workforce benefits enormously from the contribution made by staff from across the EU. The free movement of people from the EU and EEA allows skilled and experienced health professionals to work in our NHS, where they fill skilled vacancies in hard to recruit specialisms and geographical regions. Many EU citizens work in social care, in roles that may be low skilled or relatively low paid and so would likely fall below the thresholds in the non-immigration system. We need to retain the ability to recruit from this diverse and experienced talent pool in order to be able to continue to provide high-quality services.

- As BMA Scotland Chair Dr Peter Bennie has said: "The Scottish Government has been clear that it wants to protect the rights of European NHS staff and this is welcome and appreciated by many, but it is ultimately the Westminster Government that must act before further damage is done." (BMA release, 14 November 2017).

- In addition to workforce issues, Brexit also raises concerns in areas such as medicines, medical devices and clinical trials, access to future EU funding and the rights of Scottish citizens to access state-provided healthcare across the EU.

- The Scottish Government is continuing to make representations in all these areas and is working hard to mitigate risks and potential implications, in the context of a situation that is fluid and rapidly developing.

Background

General

- The UK will exit the EU on 29 March 2019, following the result of the referendum on EU membership in June 2016. The UKG and EU sides agreed on a transition period at the European Council on 22-23 March, during which current rules will continue to apply until 31 December 2020, to coincide with the end of the current financial framework period.

- On 8 December 2017 the EU and UK published the *Joint Report From the Negotiators of the European Union and the United Kingdom Government*, outlining the matters that have been concluded during the current phase of Brexit negotiations. Importantly, this report details the common understanding that has been reached between the UK Government and the European Union on EU citizens' rights.

- The aim is that negotiations on a final withdrawal agreement can be agreed by late October 2018, leaving enough time for ratification by the European and National Parliaments.

Workforce

- Brexit is clearly already damaging recruitment of European staff to the NHS. For example, a British Medical Association (BMA) survey in November 2017 reported that almost a fifth of EU doctors working in the UK have made plans to leave since the Brexit vote. Also in November 2017, the Nursing and Midwifery Council reported that the number of nurses and midwives from Europe joining the UK register had fallen by 89%.

- EU27 nationals made up 5.0% of the Scottish workforce in employment across sectors in 2016 (Annual Population Survey 2016, Office for National Statistics).

- There are 1,177 non-UK EEA-qualified doctors in Scotland, from a total of 21,609 – 5.9% of Scotland's doctors (GMC, November 2017).

- Nurses and midwives from the EEA make up around 5% of the register across the UK and all healthcare employers. Although we in Scotland rely less on EU qualified nursing than the rest of the UK (only 762 or 1.5% of the band 5 workforce), NHS Scotland is also concerned at the sharp decrease in the number of EEA nationals joining the register. The wider social care issue is also pressing – up to 8% of care home staff are EU nationals and where these staff choose not to stay there could be an impact in the median term on discharges from hospital etc.

- Despite the initial deal concluded between the UK Government and the EU in December and the March deal on the transition period, much uncertainty remains. The precise and final impact of Brexit on recruitment and retention within NHSScotland will depend on the form of withdrawal from the EU and the subsequent migration arrangements imposed by the UK Government.

- As members of the EU we have not previously been required to collect or collate information on numbers of non-UK EU citizens working within health and social care in Scotland. We do not therefore currently have accurate data on the proportion of staff working in health and social care services who are non-UK EU (EU27). Work to address the NHS workforce data issue is underway with NHS Boards and HMRC and we have commissioned work to help improve our understanding of the contribution of EU27 nationals to the social services workforce.

Mutual Recognition of Qualifications

- The Scottish Government strongly supports maintaining the EEA-wide reciprocal system of automatic recognition of qualifications for the sectoral health professions (doctors, dentists, midwives nurses and pharmacists) covered by the Directive.

- Cross border mobility and freedom of movement are essential for our health and social care workforce and retention of mutual recognition of qualifications is the best way to ensure we can continue to recruit staff from the EEA.

- As BMA Scotland Chair Dr Peter Bennie has said: "... politicians and negotiators [need] to find a solution that continues the mutual recognition of medical qualifications across Europe ... We have seen welcome commitments from the Scottish Government that they agree and support this aim and I am pleased to have their support in these discussions. The UK Government must follow suit ..." (*BMA Scotland, Press release, 23 May 2018).*

Reciprocal Healthcare

- We understand the importance of EU healthcare arrangements that allow Scots to receive necessary healthcare using the European Health Insurance Card in the event of illness or accident while travelling in the European Economic Area.

- We also recognise the considerable benefits of being able to travel in the EEA for planned treatment under the S2 scheme and of our state pensioners receiving state healthcare under the S1 scheme when they choose to live in other EEA countries.

- We continue to press the UK Government to ensure that our citizens continue to have access to those rights following the UK's withdrawal from the EU.

Medicines and medical devices

- We are concerned that the potential loss of UK participation in the European Medicines Agency (EMA) could result in patients in Scotland having slower or reduced access to new medicines. We have urged the UK Government to secure the UK's continued place within the EMA as soon as possible.

Access to EU Research funding

- Scotland, the UK and EU partners all benefit from EU research funding programmes and collaborative working. There is a risk that diminished international competitiveness and influence of the Scottish health research sector, coupled with exclusion from collaborative networks with others in the EU, may reduce the attraction of Scotland to potential collaborative partners outside the non-EU.

Trade/ Privatisation of the NHS

- Any post-Brexit trade deals the UK enters into must not open up our NHS to privatisation or endanger public health initiatives – that simply cannot and must not be allowed to happen.

Cross Border threats to health

- Brexit could result in Scotland and the UK no longer being part of EU public health structures. At this stage, and although there are many unknowns, we do not think Brexit is likely have a serious impact on Scotland's ability to respond to a cross border threat to health, as we would continue to be part of WHO arrangements.

- We continue to work closely with counterparts in the rest of the UK to understand the operational implications of EU Exit on the response to cross border threats to health, including mitigation options if the UK is no longer formally part of EU structures.

Document 8 – Extract from Briefing Document

Top lines

- Scotland's health and social care sectors benefit enormously from the contribution of staff from across the EU/EEA. We greatly value our non-UK EU/EEA citizens and their wider contribution to our society. We are working to see that their rights and place in our nation are protected. The workforce that is currently in Scotland and elsewhere in the UK should be able to stay.

- We need to retain our ability to recruit staff from inside and outside the EEA. Cross-border mobility and freedom of movement are essential for our health and social care services. We are extremely concerned that maintaining freedom of movement for the health and social care sector does not appear to be the default position of the UK Government.

- We are working hard to attract the best international talent to our universities and healthcare workforce. Any loss of EU freedom of movement would threaten our ability to attract this talent to medical and dentistry schools.

- We should press hard for continuation of the EEA-wide reciprocal system of automatic recognition of qualifications for the "sectoral" health professions (doctors, dentists, midwives, nurses and pharmacists) covered by the Directive.

Background – free movement of workers

Scotland's health and social care sectors benefit enormously from the contribution of staff from across the EU. Estimates from the Annual Population Survey indicate that EU27 nationals made up approximately 5% of the overall Scottish workforce.

As at 30 June 2017, around 1,177 of the EEA nationals licensed to practise by the General Medical Council were registered in Scotland (approximately 5.9% of Scotland's doctors); distribution varies by specialism. Around 4% of nurses are estimated to be from EEA countries, though data provided by the NMC suggests that only 1.76% of the registered nursing workforce in Scotland is from the EEA. 2% of dentists in training are from the EU, though UK-wide statistics suggest EEA nationals could be a much higher proportion of the dental workforce. The percentage of people employed within adult social care and childcare that are non-UK EU nationals is 5.6%, which equates to 9,830 workers.

The European Commission's regulated professions database indicates that, during the period 1997-2016, over 70,000 doctors moved from one EU country to another, of which almost 25,000 moved to the UK from another EU member state. During that period, only 1,750 doctors moved from the UK to another EU member state. Equally some 73,000 nurses moved from one EU country to another during the same time period, of which almost 35,000 moved to the UK from another EU member state, with just over 3000 moving from the UK to another EU member state.

Overall, the UK has benefitted more than any other member state (and considerably so) from inward migration in relation to the clinically regulated professions. Further information and infographics are provided in the following article: http://www.politico.eu/article/doctors-nurses-migration-health-care-crisis-workers-follow-the-money-european-commission-data/

The free movement of workers, and the absence of immigration controls, has made the EU an important and attractive recruitment market for health and social care employers. The removal of free movement rights for workers will have a potentially significant impact on the health and social care sector, and will provide even greater challenges in ensuring that it can attract and retain the workforce it needs.

While some steps can and are being taken[1] in relation to training numbers to address future workforce need, we will not reach a position where we are able to find all of the medical workforce we need from within the UK without retaining the ability to recruit internationally, either from the EU or beyond. The nature of medical training, and in particular the comparatively high level of mobility of senior clinicians, means that, if you put an undergraduate medical student into the system today, it will be a minimum of 10 years before that student is a qualified GP, and training pathways are considerably longer in other specialties. Increasing undergraduate provision can only provide a potential solution to workforce issues in the longer term, and will not address ongoing challenges in the short to medium term.

We need to ensure that we can retain the EU workforce already employed within the health and social care sectors, and we also need to ensure that any future immigration arrangements enable the sector to continue to recruit workers from the EU and beyond. Any future immigration arrangements will need to ensure that routes remain open to recruit staff at all levels – and that any system does not prevent the health and social care sector from recruiting staff to fill vital nursing and healthcare support worker roles. This will include individuals within the NHS, but also in the wider care sector including roles which have traditionally been classed as low skill roles within the migration system. There are additionally concerns that a future migration system will impose higher application fees than those currently in place for EU/ EEA citizens seeking permanent residence under EU law (currently £65). Where it becomes materially more expensive to apply for the right to remain in the UK, this is likely to act as a significant disincentive for low and moderately paid members of the workforce.

Related to this is the ability of our medical schools to attract students to study medicine and dentistry. At present, non-UK EU students enjoy free tuition fees, which has made Scottish medical and dental schools more attractive to EU students. The introduction of tuition fees and immigration controls for these students could deter them from applying to study medicine and dentistry in Scotland. We would like to see these rights retained under any future arrangements as this will help maintain the attractiveness of medical teaching in Scotland in what is a highly competitive market and, through the quality educational experiences gained within NHS services, greatly assist NHS Boards in their on-going efforts to recruit and retain a motivated and highly skilled workforce.

[1] In Part 1 of the National Health and Social Care Workforce Plan, Ministers committed to increasing medical undergraduate places by 50-100 over the course of this parliamentary term.

It will also be important to retain social protection and employment legislation, including laws relating to health and safety and equality and diversity in the workplace, as well as family-friendly policies and parental rights, much of which, at a domestic level, is currently reserved to the UK Government. Any negotiations between the UK and Scottish Governments should seek to ensure that these protections remain in place.

Background – mutual recognition of professional qualifications

The single EU competence that directly influences health professional regulation in the UK is the common framework of minimum education standards and training components, as harmonised in 2005/36/EC, The Directive on Recognition of Professional Qualifications as amended by 2013/55/EU. This facilitates free movement of members of all professions regulated by law in the majority of member states under two systems:

i. The so-called "sectoral" professions, i.e. doctors, nurses, dentists, midwives, pharmacists, architects and veterinarians, which benefit from automatic recognition of their home state qualifications by the host state in which they wish to practise their profession.

ii. The "General System", which applies to those professions regulated by law in the majority of member states but not subject to specific legislation, including graduate social workers and some other groups within the social care workforce. (All other professionals, including professional social workers, other regulated parts of the social services workforce as well as additional non-sectoral healthcare professions under the general provisions.) The regulatory authorities for these professions may require applicants to undertake adaptation traineeships and/or aptitude tests to address differences in education, competencies and scope of practice in applicable qualifications from other member states.

Free movement within current European single market arrangements allows EEA nationals to *live* in the UK, but recognition of their qualifications is required in order for EEA health professionals (including UK nationals who trained outside the UK) to attain the registration necessary to practise their profession. It is a criminal offence to practise a regulated health profession without current registration.

The administrative and bureaucratic advantage of the current system is that the General Medical Council has a secure intra-EU system for verifying the qualification status of applicants, which significantly reduces the length of time it takes for the GMC to be able to register a medical professional and certify their fitness to practice. Losing this could build in delays to this process, such as are occasionally experienced when recruiting from elsewhere.

Any divergence from the harmonised minimum training requirements could be expected to be an upwards pressure for EU applicants. While increasing the requirements might not impact adversely (at least initially) on UK-trained professionals who seek to work in an EEA Member State, it could reasonably be assumed to lead to a reduction in the number of regulated professionals applying for UK registration.

The SG therefore wishes strongly to retain recognition of professional qualifications for the regulated healthcare professions, and for the Home Office to facilitate a simplified

immigration process for members of the health and social care professions, perhaps through a mechanism similar to the current Shortage Occupation List. At the very least, those already living and working in the regulated professions in Scotland must be given leave to remain, which was a commitment contained in the Prime Minister's open letter to EU citizens living in the UK on 18 October 2017.

Top lines – EU regulation of medicines, medical devices and clinical trials

- Crucial that UK remains within the European Medicines Agency (EMA) and continues to secure access to the EU Clinical Trials Portal.

- We must ensure cross-border trade on medical products such as the medical radioisotopes that are critical for cancer treatment, is as frictionless as possible. The Scottish Government would therefore encourage a close and effective future association with Euratom.

- Clear risk of pharmaceutical companies being less attracted to the UK market (vs larger EU and US markets), potentially resulting in delays to patients getting access to the medicines they need. Medicine manufacturers could be negatively impacted by additional costs as a result of having to work separately with the UK. This may mean that some manufacturers choose not to do so at all.

- Crucial that the UK agrees mutual recognition of the CE – mark scheme for medical devices. Medical devices require multiple components and quality checking in many different EU countries. Specialist skills are required for this work, and these skills must be maintained if Scotland is to continue to provide high quality care and the businesses producing the devices are to flourish.

- The new EU-wide regulatory framework for medical devices - adopted in 2017 - will only be fully operational by 2020 (and in 2022 for in-vitro medical devices). It is vital that the UK ensures full adoption of – or full alignment to – the new regime to provide certainty to the sector, deliver benefits to patients including enhanced pre-market clinical evidence and coordinated post market surveillance, and support the economic growth of the large number of small and medium sized businesses in Scotland.

Top lines – EU regulation of products with serious health impacts (especially food safety and tobacco products)

- Maintain common pan-European approach to food safety and standards, maintaining a high level of consumer protection and keeping Scotland's producers and markets aligned with European regulatory frameworks, with continued access to the European Food Safety Authority;

- Press for no reduction in consumer information standards as a result of Brexit, whereby the relevant EU legislation would be incorporated into UK law and ensuring

that consumer information can continue to be a mechanism to drive public health improvements;

- Scotland's devolved approach to tobacco control regime is internationally-recognised and separate from that of the rest of the UK, where there is potential for watering down of current restrictions. Tackling the harms of tobacco is more of a priority for Scotland. We must try to maintain restrictions and responsibilities for tobacco products at current European levels following the transfer of this devolved area of responsibility from Europe to the UK Government.

Background – regulatory regime for medicines and medical devices

The European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision and safety monitoring of human and veterinary medicines developed by pharmaceutical companies for use in the EU. It provides independent, science-based information on medicines, assessing them for market authorisations and monitoring their safety whilst working to improve access to innovative medical products.

The Scottish Government supports a position where the UK would remain as a member of the EMA and is concerned at the potential damage the loss of UK participation could result in, such as slower or reduced access to new medicines for patients. There has been no confirmation on whether the medicines currently licensed by the EMA would remain licensed in the UK if it leaves the EMA.

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) currently undertakes around a third of all licensing on behalf of the EMA, however one key concern is that by removing itself from the EMA, the UK could be relegated to a similar position to countries such as Canada and Switzerland who are routinely behind the EU and US in the priorities of pharmaceutical companies. This could lead to potential delays of a number of months. The additional expense to the manufacturers of having to work separately with the UK could also make it less attractive and may drive up costs.

The UK medical device market is the third largest in Europe. The current system of approval of medical devices in the UK automatically extends approval to the rest of the EU for products with a CE mark. The UK's Notified Bodies provide the conformity assessment of 40% of high risk implantable products on the EU market.

The new EU Medical Devices Regulations for medical devices and in-vitro medical devices were adopted in 2017 and will be fully in force by 2020 for medical devices and 2022 for in-vitro medical devices. If the UK leaves the EU in 2019, some of the necessary changes will not yet be in place, which could cause uncertainty regarding the future regulatory environment. This uncertainty could lead to patient safety issues and a lack of markets for the small and medium sized enterprises in this sector that are helping to grow the Scottish economy.

The Cabinet Secretary for Health and Sport wrote to the UK Secretary of State for Health on 24 July 2017 to set out the concerns above and to seek clarity on the UK's preferred future

relationship with the EMA. The Welsh Government have also written in similar terms to the UK Government.

UK position on medicines and medical devices

The Secretary of State for Health wrote a joint letter with the Secretary of State for Business to the Financial Times on 4 July 2017 to "provide assurance" over the UK Government's future plans on the regulation of medicines and devices. The letter outlined the 3 principles which will underpin the development of a post-Brexit regulatory system for medicines and devices: patients should not be disadvantaged; innovators should be able to access the UK market as quickly and simply as possible; and MHRA will continue to play a leading role in both Europe and the world in promoting public health. The letter offered "close collaboration" with the EU around patient safety and regulation, as well as a pledge to "continue to work closely with the EMA and our international partners" to ensure that new medicines will continue to reach patients quickly. On 31 August 2017, Lord O'Shaughnessy, UK Parliamentary Under-Secretary of State for Health, responded to the Cabinet Secretary's letter to indicate that it is their intention to retain continued cooperation with the EMA, with patient safety at the heart of any final decision.

The Prime Minister's Mansion House speech (2 March) publicly confirmed the UK Government's preferred outcomes, stating 'trade at the UK-EU border should be as frictionless as possible', no 'introduction of tariffs or quotas', and as now 'products only need to undergo one series of approvals, in one country, to show that they meet the required regulatory standards'. An implementation period has been agreed through to end December 2020 (subject to ratification).

Background - regulation of clinical trials

The regulation of clinical trials involving medicinal products for human use is currently within the agreed competence of the EU (the free movement of goods eg medicinal products is within the EU's exclusive competence; the promotion of research and technological development is shared competence). At a UK level, the regulation of clinical trials involving medicinal products for human use is reserved to the UK Government/Parliament. Additional powers for these matters returning to the UK would therefore rest with the UK Government/Parliament under existing constitutional arrangements and would not relate to a devolved competence being centralised to Westminster. The UK Government has indicated that, post-Brexit, its negotiating position would be to seek to continue to operate within the ambit of relevant EU clinical trials legislation, including access to supporting IT infrastructure, in the interests of continued cross-border working and to facilitate an on-going single market in medicinal products. We support the UK Government's negotiating position which would benefit Scotland as a research base.

Background – regulation of products with serious adverse health impacts (especially food safety and tobacco products)

If the UK decides to repeal or amend food information or tobacco products regulations this could have serious implications for the health of people in Scotland. Smoking is our leading cause of cancer and the leading avoidable cause of death - it kills half of all smokers. It causes around 12,000 deaths per year in Scotland. Current regulations have contributed to a significant drop in the proportion of people smoking in Scotland – a rate which has dropped from 31 per cent to 21 per cent in ten years.

Regulation of food

Food-borne disease and food poisoning account for almost 60,000 hospitalisations per year in Scotland, and bad diet and obesity (over two thirds of people in Scotland are overweight or obese) are both growing concerns which food information can help combat. There are two particular areas that we continue to keep a close watching brief: (a) the European Food Safety Agency which provides independent scientific risk assessment to EU Member States and the Commission, to inform risk management decisions relating to food, covering general food hygiene requirements, meat hygiene, food safety and animal feeding stuffs; and (b) the Food Information for Consumers Regulations which provide harmonised rules for food labelling and how food information is provided to consumers. These matters are currently devolved and Scotland has its own sets of Regulations to give effect to these, which differ in some aspects from the Regulations in England and Wales in how they are applied and enforced. The internal UK arrangements will continue to be important to take into account in changes as a result of powers and responsibilities in these areas returning to the UK.

Regulation of tobacco related products

The regulation of tobacco products including cigarettes and nicotine vapour products (including electronic cigarettes) is a policy area in which Scotland has a proud record. The public health aspects of tobacco products are devolved but the consumer protection aspects are reserved. For the public health policies, our strategies and actions are mostly distinct from or in place well in advance of activities in the rest of the UK. Many recent restrictions such as standardised plain packaging of cigarettes and the ban on advertising nicotine vapour products will be under threat when responsibility for the policy returns to the UK following Brexit. Support for these important restrictions was never as strong in England as here in Scotland.

Background

Funds from Horizon 2020, the EU Research and Innovation programme, provide opportunities for Scottish researchers to be involved in wide ranging international collaborative research activities: to develop new more effective ways to diagnose and treat diseases; to drive health system innovation; or to address some of the most pressing health threats and challenges of our time.

Almost €333m of Horizon 2020 funding has been secured by Scottish organisations with a significant proportion of this for health-related research. Brexit brings the real possibility of creating a research funding gap - only 7% of research money allocated by the EU and

European Research Council in the past decade has gone to non-member states. It is not only the scale of funding that is significant, but also the locomotive effect that resources have to drive collaboration and forge partnerships that allow our researchers to achieve more than they would alone.

Scotland attracts over 30% more of UK public research funds than our population share would suggest, this could be at risk if Brexit impacts on the UK's wealth in the short to medium term and on the money available for healthcare and research.

The European Research Council (ERC), which is part of Horizon 2020, has established a renowned international reputation for funding "frontier research purely on the basis of scientific excellence". The UK is the top performer in terms of accessing these funds.

Over the period from 1st January 2012 to 31st December 2014, researchers funded by 13 Association of Medical Research Charities received over £260 million in EU funding. Examples of the substantial nature of this funding for individual charities include: Arthritis Research UK (ARUK > £18 million of European funding for research into musculoskeletal (MSK) arthritis 2011-14); Alzheimer's Research UK (European Commission is the 4th largest funder by number of the charity's grants and 7th largest funder ranked by size of grant)[4]; and Cancer Research UK institutes across the UK (received £7.5 million income from EU grants in 2014-15, which accounted for nearly 7% of their total research funding). The Royal Society, Academy of Medical Sciences, Medical Schools Council and others are concerned that UK researchers may be excluded from future EU consortia due to a perception that they are now less likely to be awarded funding.

While the UK could pay into the EU science budget and apply for funds (similar to Israel and Switzerland) this would be less easy to manage than the current situation. There is also a concern that UK partners will be given less opportunity by other collaborators due to a perception of being not fully engaged.

It is worth noting that the UK is probably the strongest research nation across the EU in most spheres (clinical trials; basic research that informs clinical medicine; epidemiology; health services research). This can be demonstrated by simple citation metrics and the standing of Universities. This also means that EU colleagues may miss input from Scottish and UK researchers who contribute significantly to collaborative research within European centres. European collaborators currently remain keen to work with Scotland's world-leading researchers, but it is difficult to know if this will continue once the Uk has withdrawn from the WEU.

Background

There are currently four EU-wide health schemes that the UK participates in at Member State level:

- The European Health Insurance Card (EHIC) - necessary treatment during a short term visit throughout the European Economic Area (EEA) and Switzerland.
- The S2 Scheme - planned treatment throughout the EEA and Switzerland.

- The S1 Scheme - state treatment for EEA State Pensioners (and short-term workers) living in other parts of the EEA and Switzerland.
- The European Cross-border Healthcare Directive that allows EEA citizens to travel throughout the EEA for healthcare and to be reimbursed by their state healthcare provider on return.

Iceland, Liechtenstein and Norway participate in the schemes through their EEA membership. Switzerland participates in the EHIC, S1 and S2 schemes through its bilateral agreements with the EU. It does not participate in the cross-border arrangements under the European Cross-border Healthcare Directive.

State healthcare provision for Scottish citizens in other EU/EEA countries is currently funded by the UK Government through EU co-ordination of social security arrangements under EU Regulation 883/2004. It is estimated that the total cost of Scottish citizens accessing healthcare under the S1 scheme (healthcare for state pensioners); the S2 scheme (planned treatment); and the European Health Insurance Card (necessary treatment) is approximately £50 million per annum. The bulk of this sum - around £48 million - is for the healthcare of UK state pensioners from Scotland who are residing in other EU countries (estimated to be approximately 15,000).

To-date representations about the future of European healthcare have mainly been around the European Health Insurance Card (EHIC), which entitles access to necessary treatment in the event of illness or accident during a short-term visit to an EEA country or Switzerland.

The EHIC costs around £1 million in total each year for Scottish citizens that use it in other EEA countries during short-term visits. (Important to note it is not a substitute for independent health insurance. For instance it does not cover repatriation costs).

Very few (less than 25 Scottish residents each year) use the S2 scheme to travel for planned healthcare in the EEA or Switzerland, again, at a total cost of around £1 million each year.

Each year around 100 Scottish residents use the European Cross-border Healthcare Directive to travel for healthcare that is the same as or equivalent to treatment available on the NHS. The patient pays for the treatment up-front and is reimbursed by their NHS Board on their return, up to the amount it would have cost had it been provided by the NHS. Eastern Europeans who have family or cultural ties to their home countries are major participants in cross-border healthcare under the Directive.

The future of state healthcare arrangements for UK state pensioners residing in other Member States is a potential issue. While it has been agreed by the EU and the UK that the status of EU nationals and Britons living elsewhere in the EU is a priority for the Brexit negotiations, it remains to be seen whether healthcare provision for EU state pensioners living in other Member States will be considered separately, either on its own or as part of wider co-ordination of social security arrangements under EU Regulation 883/2004.

SG officials have spoken to their counterparts in the European Healthcare team in the Department of health, but they have been unwilling or unable to provide any information

regarding UK negotiating positions on the future of state healthcare insurance arrangements for both UK citizens residing in or travelling to the EU and EU citizens living or travelling in the UK.

As the EU health insurance schemes are intrinsically linked to the EU founding principles of freedom of movement, access to goods and services and the single market, it is very difficult to see how the UK could continue to participate in them in their present form with a hard Brexit.

Document 9 – Extract from Health and Sport Committee Briefing

Background

Workforce

- In 2017, there were 1,177 **doctors** with a European Primary Medical Qualification (PMQ) living in Scotland, this equates to some 5.9% of the workforce (i.e. of 19,992 registered and licensed doctors in Scotland) . This is lower than the average UK-wide, which is 9.1% of all licensed doctors.
- Nevertheless, some 573 doctors with a European PMQ living in Scotland are on the specialist only register, representing some 9.3% of all clinical specialists.
- As a proportion of NHSScotland establishment, EEA qualified doctors are overrepresented in the following specialisms: Medicine (9.3%); Emergency Medicine (7.4%); Anaesthetics and Intensive Care (9.4%); Occupational Medicine (10.4%); Ophthalmology (8.7%); Paediatrics (9.8%); Pathology (12.7%); Radiology (10.5%); Surgery (13.9%): Other/Multiple Specialties (15.4%).
- There has been no reduction so far in the number of EEA graduates on the medical register since the referendum itself, nor in the number of EEA graduates who have joined the medical profession – however it remains too early to be certain what impact any changes to the UK's relationship with the EU might have on the data in the medium/longer term.

- At 30/09/2017 there were 762 **nurses and midwives** registered with an address in Scotland whose country of initial registration was outside the UK, but within the EU/EEA.

- This equates to some 1.76% of the qualified nursing and midwifery workforce in Scotland. *[i.e. those working at Agenda for Change Band 5 or above; total workforce in these pay bands is: 43,249.5]*

- Estimates from the 2016 Annual Population Survey suggest that EU citizens comprise 4.4% of the social work sector workforce in Scotland, and non-EU national a further 2.4% of the combined health and social work sector.
- Scottish Care surveys suggest that there is a slightly higher proportion of workers from other EU countries in the independent care home sector (6%) and anecdotally, approximately 8% in the independent 'care at home' and housing support services sector, suggesting that some subsectors within social services are more dependent on non-UK EU workers.

Mutual Recognition of Qualifications

Background - The EU Directive on Recognition of Professional Qualifications

The Directive established the current arrangements under which regulated professionals can have their home qualifications recognised by the host state in which they wish to work. The system is built on the pillars of:

- Automatic recognition of seven "sectoral" professions;
- Recognition of work experience in crafts, trade and industry;
- The General System

So-called "automatic recognition" depends on close adoption of criteria for both duration and content of undergraduate training programmes, as set out specifically in the Directive. Automatic recognition applies only to the seven "sectoral systems", being: **doctors; dentists; midwives; general care nurses; pharmacists**; veterinary surgeons and architects.

For some professional activities in crafts, trade and industry, the recognition system is based on professional experience, but for all other regulated professions the General System applies. The scope of practice, level and content of primary qualifications, and even the description and/or title of General System professions may vary significantly between member states. In such cases the host state is permitted to require that applicants for registration undertake a period of defined adaptation measures to bring them up to local standards, or to sit a practical test and/or theoretical examination to demonstrate their competence.

Different rules apply when regulated professionals wish to work in the UK on only a temporary and occasional basis. To be eligible for this type of registration, professionals must be a citizen of an EEA country or Switzerland (or otherwise hold European Community rights), currently established and permitted to practise without restriction in another EEA country, and intended practice must be both temporary and occasional, which means not on a regular, frequent or continuous basis, for which full registration is required.

Examples of the kind of provision of services that might be considered temporary and occasional include:

- A sports doctor or physiotherapist accompanying a team or individual to UK sports fixtures.
- Public health professionals assisting in a national emergency
- A health professional coming over to the UK to treat a friend or family member.

Legislation and applicability

The system was established by Directive 2005/36/EC and amended by 2013/55/EU. The Directive's provisions apply to the EU28 and three EEA countries (and Switzerland), by virtue of Annex III of the EU/Switzerland bilateral Agreement on the Free Movement of Persons (AFMP)). The provisions of the Directive are transposed to UK domestic law by The European Union (Recognition of Professional Qualifications) Regulations 2015.

Implications of EU departure on professional regulation of the health and social care workforce

The system of "automatic recognition" for the five health sectoral professions facilitates a very much quicker route to professional registration for EEA (and Switzerland) applicants than current processes for international or "overseas" applicants.

Defaulting to international processes for all applicants would place an unsustainable administrative burden on the regulators responsible for the sectoral health professions, leading in turn to significant delays in healthcare professionals being able to take up posts in the UK. Concerns about recruitment pressures are common to healthcare employers across the UK in both the national, independent and voluntary sectors.

Current position

Regulatory policy officials attended a four country discussion on 13 February, which confirmed that the potential risks to recruitment outlined above are recognised and shared by counterparts. Admitting the "have your cake and eat it" approach, Department of Health and Social Care (DHSC) officials confirmed their Secretary of State's wish to maintain arrangements as close as possible to the current system at least until the end of the negotiated transition period and, ideally, for up to eight years, until such time as the UK might be self-sufficient with a "home grown" sectoral professional workforce.

While supportive of this intention, Devolved Administration colleagues expressed the common concern that self-sufficiency for England did not necessarily translate across the UK, given the significantly greater peripheral recruitment pressures.

Regulators have also expressed concerns about constraints on their registration processes arising from the legislation which transposes the provisions of the Directive into domestic (UK) law and DHSC counterparts confirmed that legislative drafting contingent to this was underway.

Reciprocal Healthcare

BACKGROUND

Regulation (EC) 883/2004

Under European co-ordination of social security legislation - Regulation (EC) 883/2004) - EEA and Swiss nationals who become ill or have an accident during short trips to other EEA countries and Switzerland can receive state healthcare on the same basis as citizens of that country, using the EHIC. This includes treatment for long term conditions, for instance dialysis, and maternity services.

Under Regulation 883/2004, EEA and Swiss State Pensioners can reside in other EEA countries and Switzerland and receive state healthcare on the same basis as citizens of their country of residence under the S1 scheme. In certain circumstances, short-term workers can also use the S1 provisions.

Under Regulation 883/2004, EEA and Swiss nationals can, in certain circumstances, travel for planned state healthcare in other EEA countries and Switzerland under the S2 scheme.

Funding

Funding flows between EEA States. The home state pays for its nationals who receive treatment under the EHIC, S1 and S2 in other parts of the EEA. And receives reimbursement for treatment provided for incoming EEA nationals under those schemes.

As the arrangements apply at Member State level the UK Government funds EU healthcare on a UK-wide basis (**at a cost of around £650 million per annum)** for UK nationals who receive healthcare in other EEA countries under the various schemes. This is off-set by income from EEA nationals who receive healthcare in the UK, although income is much smaller, perhaps **£70 million per annum**. The EHIC, S1 and S2 Schemes are also administered on a UK-wide basis by the Department for Work and Pensions.

We estimate that Scots account for approximately £50 million of the cost to the UK for EU healthcare each year. The bulk of that sum (about £48 million) is for the healthcare of around 15,000 state pensioners from Scotland who have chosen to reside in other parts of the EEA.

If there is a final agreement by the UK government and the EU to continue the existing arrangements under the co-ordination of social security legislation. Then we would expect the UK Government to continue to fully fund and administer the various schemes.

European Cross-border Healthcare Directive

Under the Directive on the Application of Patients' Rights in Cross-Border Healthcare, in certain circumstances, EEA citizens can obtain treatment in another Member State,

including private healthcare, that is the same as or equivalent to healthcare that is provided by their home state health system - in Scotland the NHS.
They then have a right to claim reimbursement on return to their home state, in Scotland from their NHS Board, up to the cost of the treatment to the NHS had it been provided at home.

Medicines and Medical Devices

Medical Devices

Background – Medicines and Medical Devices

Regulation for the licensing, safety and efficacy of medicines is currently reserved to the UK Government under the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA) who operate on a UK-wide basis.

The European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision and safety monitoring of human and veterinary medicines developed by pharmaceutical companies for use in the EU. It provides independent, science-based information on medicines, assessing them for market authorisations and monitoring their safety whilst working to improve access to innovative medical products.

The Scottish Government supports a position where the UK would remain as a member of the EMA and is concerned at the potential damage the loss of UK participation could result in, such as slower or reduced access to new medicines for patients. There has been no confirmation on whether the medicines currently licensed by the EMA would remain licensed in the UK should the UK leave the EMA.

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) currently undertakes around a third of all licensing on behalf of the EMA, however one key concern is that by removing itself from the EMA, the UK could be relegated to a similar position to countries such as Canada and Switzerland who are routinely behind the EU and US in the priorities of pharmaceutical companies. This could lead to potential delays of a number of months. The additional expense to the manufacturers of having to work separately with the UK could also make the UK less attractive and may drive up costs.

The new EU Medical Devices Regulations for medical devices and in-vitro medical devices were adopted in 2017 and will be fully in force by 2020 for medical devices and 2022 for in-vitro medical devices. If the UK leaves the EU in 2019, some of the necessary changes will not yet be in place, which could cause uncertainty regarding the future regulatory environment. This uncertainty could lead to patient safety issues and a lack of markets for the small and medium sized enterprises in this sector that are helping to grow the Scottish economy.

You wrote to Jeremy Hunt on 24 July 2017 to set out your concerns and to seek clarity on the UK's preferred future relationship with the EMA. In his response, Lord O'Shaughnessy confirmed that it was the UK Government's position to "retain continued cooperation with the EMA" but that this would be subject to negotiations and that, in any case, "there will be a regulatory system that protects the public". In addition to your Scottish Parliament evidence you have also provided written evidence to the House of Commons Health Select committee inquiry to ensure that Scottish patients were represented and taken into consideration.

Access to EU research funding

Background

Funds from Horizon 2020, the EU Research and Innovation programme that includes (but is wider than) health research, provide opportunities for Scottish researchers to be involved in wide ranging international collaborative research activities to develop new more effective ways to diagnose and treat diseases; to drive health system innovation; or to address some of the most pressing health threats and challenges of our time.

Scottish Higher Education Institutions have secured over €316.5 million under Horizon 2020 (up to September 2017) based on our world-class research, with a significant proportion of this for health-related research. Brexit brings the real possibility of creating a research funding gap - only around 7% of research money allocated by the EU and European Research Council in the past decade has gone to non-member states. It is not only the scale of funding that is significant, but also the locomotive effect that resources have to drive collaboration and forge partnerships that allow our researchers to achieve more than they would alone.

Scotland attracts over 30% more of UK public research funds than our population share would suggest, this could be at risk if Brexit impacts on the UK's wealth in the short to medium term and on the money available for healthcare and research.

Regulation of Clinical Trials

Background

The regulation of clinical trials involving medicinal products for human use is currently within the agreed competence of the EU (the free movement of goods eg medicinal products is within the EU's exclusive competence; the promotion of research and technological development is shared competence). Such clinical trials are currently subject to the EU Clinical Trials Directive (2001/20/EC). That Directive will become a directly binding EU Clinical Trials Regulation in 2019. The new EU Regulation will **harmonise the assessment and supervision processes for** clinical trials **throughout the EU, via an EU portal and database. The European Medicines Agency (EMA) will set up and maintain the portal and database, in collaboration with the Member States and the European Commission.**

At a UK level, the regulation of clinical trials involving medicinal products for human use is reserved to the UK Government/Parliament. Additional powers for these matters returning to the UK would therefore rest with the UK Government/Parliament under existing constitutional arrangements and would not relate to a devolved competence being centralised to Westminster. The UK Government has indicated that, post-Brexit, its negotiating position would be to seek to continue to operate within the ambit of relevant EU clinical trials legislation, including access to supporting IT infrastructure such as the clinical trials portal and database, in the interests of continued cross-border working and to facilitate an on-going single market in medicinal products. We support the UK Government's negotiating position which would benefit Scotland as a research base.

One of the significant reasons for this is that under the International Health Regulations (i.e. international law, rather than EU law), the UK and other EU countries already have to provide notifications on any disease outbreaks or other incidents which pose a serious threat to health via World Health Organisation mechanisms.

Another significant reason is that the UK public health organisations' expertise is well regarded in Europe, and professional relationships between experts in the UK and experts in other parts of Europe are very strong – the UK is seen as being firmly in the "top tier" of health protection expertise in the EU, along with France, Germany and the Nordics. It is common for UK professionals to be asked to contribute to and peer-review risk assessment and other work carried out, and there is confidence that these professional relationships will be maintained because of the expertise the UK has to offer.

ORGANS, TISSUES AND CELLS AND BLOOD

Background

Policy on donated organs, blood and tissues and cells for transplantation are devolved to the Scottish Parliament (excluding reproductive cells, such as sperm/gametes as policy on this reserved), although the existing EU Directives and Commission Decisions in these areas are all implemented through UK wide regulations. In all cases, there are UK wide regulators which license bodies involved in donation, storage or transplantation – the Human Tissue Authority (HTA) for organs, tissues and cells (excluding reproductive cells) and the Medicines and Healthcare products Regulatory Agency (MHRA) for blood. For organs and some tissue (such as pancreatic islets and currently eyes) there is also one UK organisation responsible for donation and allocation, NHS Blood and Transplant (NHSBT). However, for blood and some tissue, the Scottish National Blood Transfusion Service manages donation for Scotland, although it works closely with NHSBT and the Welsh and Northern Irish blood services to common safety standards.

The Minister for Public Health and Sport has agreed that, post Brexit, existing arrangements should continue, with UK wide regulations maintaining existing EU standards of safety and quality of donated organs, blood and tissues and cells. However, following initial informal discussions with the UK Government, Welsh Government and Northern Irish administration, it is expected that there will be a Memorandum of Understanding to set out agreed procedures to follow when one of more administration wishes to amend any of the existing regulations, including requiring the Department of Health to consult us before proposing any amendments.

We have also signalled to the Department of Health that the Scottish Government might potentially want to take forward separate Scottish regulations in future and so we would look for the MOU to agree a mechanism to enable this.

On 27 February 2018, the Scottish Sun reported 'Tory chiefs blasted for suggesting Scotland could refuse to share donated organs with England after Brexit' following Cabinet Office Minister David Lidington's speech on 26 February regarding the EU Withdrawal Bill. Mr Lidington confirmed in response to the Sun that his reference to the importance of continued intra-UK working was just an example, but it is worth noting that there has never been any disagreement about organ quality and safety regulations continuing to operate at UK level post Brexit. Nor has there been any suggestion that Scotland would seek to avoid sharing organs across the UK (in fact, most years, Scotland benefits from the UK wide allocation system, with patients in Scotland receiving more organ transplants from deceased donors than the number of deceased donor organs donated in Scottish hospitals).

IMPACT OF BREXIT ON HEALTH AND SOCIAL CARE IN SCOTLAND

TOP LINES

- The Scottish Government believes that Brexit represents a significant threat to the UK's and, in particular, to Scotland's future economic and social prosperity. At present, considerable, and damaging, uncertainty characterises both the negotiations and the UK Government's ultimate objectives with regard to the future relationship with the EU.

- Scotland's health and social care sectors benefit enormously from the contribution of staff from across the EU. We greatly value our non-UK EU citizens and their wider contribution to our society and we are working to see that their rights and place in our nation are protected.

- In August 2017 I wrote to the Home Secretary to raise concerns about the approach being taken to Brexit and a number of recent immigration policy changes introduced by the UK Government, which are detrimental to NHS Scotland's ability to recruit and retain international workers.

- In addition to workforce issues, Brexit also raises concerns in areas such as medicines, medical devices and clinical trials, access to future EU funding and the rights of Scottish citizens to access state-provided healthcare across the EU.

- The Scottish Government is continuing to make representations in all these areas and is working hard with NHS Boards and other partners to mitigate risks and potential implications, in the context of a situation that is fluid and rapidly developing.

Mutual Recognition of Qualifications

- The Scottish Government strongly supports maintaining the EEA-wide reciprocal system of automatic recognition of qualifications for the sectoral health professions (doctors, dentists, midwives nurses and pharmacists) currently covered by EU legislation.

- Cross border mobility and freedom of movement are essential for our health and social care workforce and retention of mutual recognition of qualifications is the best way to ensure we can continue to recruit staff from the EEA.

Reciprocal Healthcare

- We understand the importance of EU healthcare arrangements that allow Scots to receive necessary healthcare using the European Health Insurance Card in the event of illness or accident while travelling in the European Economic Area.

- We also recognise the considerable benefits of being able to travel in the EEA for planned treatment under the S2 scheme and of our state pensioners

receiving state healthcare under the S1 scheme when they choose to live in other EEA countries.

- We continue to press the UK Government to ensure that our citizens continue to have access to those rights following the UK's withdrawal from the EU.

Medicines and medical devices

- We are concerned that the potential loss of UK participation in the European Medicines Agency (EMA) could result in patients in Scotland having slower or reduced access to new medicines. We have urged the UK Government to secure the UK's continued place within the EMA as soon as possible.

Access to EU Research funding

- Scotland, the UK and EU partners all benefit from EU research funding programmes and collaborative working. There is a risk that diminished international competitiveness and influence of the Scottish health research sector, coupled with exclusion from collaborative networks with others in the EU, may reduce the attraction of Scotland to potential collaborative partners outside the non-EU.

Trade/ Privatisation of the NHS

- I wrote to the Prime Minister on the 20th March 2018 to express my disappointment at her failure at Prime Minister's Questions on 7 February 2018 to confirm that the NHS will not be included in post-Brexit trade negotiations with the United States.

- Any post-Brexit trade deals the UK enters into must not open up our NHS to privatisation or endanger public health initiatives – that simply cannot and must not be allowed to happen.

Cross Border threats to health

- Brexit could result in Scotland and the UK no longer being part of EU public health structures. At this stage, and although there are many unknowns, we do not think Brexit is likely have a serious impact on Scotland's ability to respond to a cross border threat to health, as we would continue to be part of WHO arrangements.

- Nevertheless, we continue to work closely with counterparts in the rest of the UK to understand the operational implications of EU Exit on the response to cross border threats to health, including mitigation options if the UK is no longer formally part of EU structures.

Document 11 - Extract from Impact of leaving the EU on the NHS Briefing for event

Background

- EU Nationals comprise approximately 5.0% of the workforce across the devolved public sector. Annual population Survey estimates (2016) indicate that this is approximately 3.5% across health and social care (c. 13,000 individuals), though the proportion is higher within certain professions and significantly higher within certain medical specialties.
- In 2017, there were 1,177 **doctors** with a European Primary Medical Qualification (PMQ) living in Scotland, this equates to some 5.9% of the workforce (i.e. of 19,992 registered and licensed doctors in Scotland). This is lower than the average UK-wide, which is 9.1% of all licensed doctors.
- Nevertheless, some 573 doctors with a European PMQ living in Scotland are on the specialist only register, representing some 9.3% of all clinical specialists.
- As a proportion of NHSScotland establishment, EEA qualified doctors are overrepresented in the following specialisms: Medicine (9.3%); Emergency Medicine (7.4%); Anaesthetics and Intensive Care (9.4%); Occupational Medicine (10.4%); Ophthalmology (8.7%); Paediatrics (9.8%); Pathology (12.7%); Radiology (10.5%); Surgery (13.9%): Other/Multiple Specialties (15.4%).
- There has been no reduction so far in the number of EEA graduates on the medical register since the referendum itself, nor in the number of EEA graduates who have joined the medical profession – however it remains too early to be certain what impact any changes to the UK's relationship with the EU might have on the data in the medium/longer term.

- At 30/09/2017 there were 762 **nurses and midwives** registered with an address in Scotland whose country of initial registration was outside the UK, but within the EU/EEA.

- This equates to some 1.76% of the qualified nursing and midwifery workforce in Scotland. *[i.e. those working at Agenda for Change Band 5 or above; total workforce in these pay bands is: 43,249.5]*

- There is limited data for the EU/EEA composition of the **allied health professions**.
- Estimates from the 2016 Annual Population Survey suggest that EU citizens comprise 4.4% of the social work sector workforce in Scotland, and non-EU national a further 2.4% of the combined health and social work sector.
- Scottish Care surveys suggest that there is a slightly higher proportion of workers from other EU countries in the independent care home sector (6%) and anecdotally, approximately 8% in the independent 'care at home' and housing support services sector, suggesting that some subsectors within social services are more dependent on non-UK EU workers.
- The SG has commissioned work, being undertaken by Ipsos-Mori, to improve our understanding of the contribution of non-UK EU nationals to the social services workforce.
- We acknowledge recruitment challenges in the sector and are working with stakeholders on a number of actions including investment in payment of the living wage and recommendations in the National Health and Social Care Workforce Plan that seek to address recruitment issues in the sector.
- Understanding the scale and contribution of workers from other EU countries in the social care sector is particularly challenging given the nature of the sector and the range of independent, voluntary and statutory organisations providing care. It is not data which has previously been required to be collected and is therefore not readily available.

Background

The joint report from the negotiators of the European Union and the UK Government on progress during phase 1 of negotiations under Article 50, published on 8 December 2017, sets out that that:

- Rules for healthcare, including the European Health Insurance Card (EHIC) scheme, will follow Regulation (EC) No 883/2004, which sets out the rules for the co-ordination of social security throughout the EU, including health.
- Persons whose competent state is the UK and are in the EU27 on the specified date and vice versa - whether on a temporary stay or resident - continue to be eligible for healthcare reimbursement, including under the EHIC scheme, as long as that stay, residence or treatment continues.
- This is also reflected in the European Commission Draft Withdrawal Agreement, published on 28 February.
- We estimate that Scots account for approximately £50 million of the cost to the UK for EU healthcare each year. The bulk of that sum (about £48 million) is for the healthcare of around 15,000 state pensioners from Scotland who have chosen to reside in other parts of the EEA.

Background

Regulation for the licensing, safety and efficacy of medicines is currently reserved to the UK Government under the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA) who operate on a UK-wide basis. The European Medicines Agency (EMA) is responsible for the scientific evaluation, supervision and safety monitoring of human and veterinary medicines developed by pharmaceutical companies for use in the EU. It provides independent, science-based information on medicines, assessing them for market authorisations and monitoring their safety whilst working to improve access to innovative medical products.

Background

Funds from Horizon 2020, the EU Research and Innovation programme that includes (but is wider than) health research, provide opportunities for Scottish researchers to be involved in wide ranging international collaborative research activities to develop new more effective ways to diagnose and treat diseases; to drive health system

innovation; or to address some of the most pressing health threats and challenges of our time.

Scottish Higher Education Institutions have secured over €316.5 million under Horizon 2020 (up to September 2017) based on our world-class research, with a significant proportion of this for health-related research. Brexit brings the real possibility of creating a research funding gap - only around 7% of research money allocated by the EU and European Research Council in the past decade has gone to non-member states. It is not only the scale of funding that is significant, but also the locomotive effect that resources have to drive collaboration and forge partnerships that allow our researchers to achieve more than they would alone.

Scotland attracts over 30% more of UK public research funds than our population share would suggest, this could be at risk if Brexit impacts on the UK's wealth in the short to medium term and on the money available for healthcare and research.

6. Cross Border threats to health

- Brexit could result in Scotland and the UK no longer being part of EU public health structures. At this stage, and although there are many unknowns, we do not think Brexit is likely have a serious impact on Scotland's ability to respond to a cross border threat to health, as we would continue to be part of WHO arrangements.
- Officials continue to work with closely with counterparts in the rest of the UK to understand the operational implications of EU Exit on the response to cross border threats to health, including mitigation options if the UK is no longer formally part of EU structures.

Background

Policy on donated organs, blood and tissues and cells for transplantation are devolved to the Scottish Parliament (excluding reproductive cells, such as sperm/gametes as policy on this reserved), although the existing EU Directives and

Commission Decisions in these areas are all implemented through UK wide regulations. In all cases, there are UK wide regulators which license bodies involved in donation, storage or transplantation – the Human Tissue Authority (HTA) for organs, tissues and cells (excluding reproductive cells) and the Medicines and Healthcare products Regulatory Agency (MHRA) for blood. For organs and some tissue (such as pancreatic islets and currently eyes) there is also one UK organisation responsible for donation and allocation, NHS Blood and Transplant (NHSBT). However, for blood and some tissue, the Scottish National Blood Transfusion Service manages donation for Scotland, although it works closely with NHSBT and the Welsh and Northern Irish blood services to common safety standards.

Document 12 – Extract from email – Securing a Healthy Brexit Deal

The full RCPSG report can be read here: http://rcp.sg/bHk0w

The recommendations in our report are:

Recommendation 1:

Applications from NHS staff to receive "Settled Status" should be expedited and prioritised for action when this process is established. The cost of this process should be met by government rather than individuals who are currently employed in the NHS.

Recommendation 2:

Future immigration rules should be set with a stated aim of maintaining and augmenting the work of the health and social care sector across the UK. This should include regular reviews of the Tier 2 Shortage Occupation Lists to ensure that specific staff shortages in the NHS are able to be addressed through this route, and that our medical research and pharmaceutical sectors also retain access to the best staff wherever they may come from.