Cabinet Secretary for Health and Sport
Shona Robison MSP

Scottish Government
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Mr Lewis Macdonald MSP
Convenor
Health and Sport Committee

Our ref:
19 June 2018

Dear Lewis,

I am writing in response to the Committee's report on the impact of leaving the European Union on health and social care in Scotland, which I have now considered, and also in line with my commitment to keep you regularly updated on EU withdrawal issues.

As we approach another milestone in negotiations with the EU, at the European Council on 28 June, I welcome the support your report gives to many Scottish Government policy positions. For example, it is right to insist – as the First Minister and I have been doing – that any **post-Brexit trade deals** the UK enters into must not open up our NHS to privatisation or endanger existing, and any future, public health initiatives. Food safety must also be given priority in future trade deals to ensure public health continues to be protected. I agree that high **EU environmental standards** in the UK have a positive impact on public health. For that reason, the Scottish Government has committed to maintaining and, wherever appropriate, exceeding EU environmental standards. I also share your concerns about possible impacts on provisions of the **Working Time Directive**, which is why the Scottish Government intends to protect the rights employees have gained under these regulations.

We have been clear that EU withdrawal represents a significant threat to the UK's and, in particular, to Scotland's future economic and social prosperity. As a result, further **financial pressures** may indeed arise post-Brexit and these could have a negative effect on **health inequalities**. We are engaging with NHS Scotland Boards in order better to understand potential financial and other implications of EU withdrawal and how best to mitigate and plan for them. In this difficult context, I will continue to focus on promoting healthy choices, fair work and physical activity and reducing tobacco and alcohol consumption and child poverty.

Turning to specific points in your report, I can confirm that a certain amount of progress has been made on **reciprocal healthcare arrangements** for EEA citizens receiving healthcare on the day the UK exits the EU. This and the continuation of other existing arrangements post-Brexit (including the European Health Insurance Card) continues to be a priority for the Scottish Government. We estimate that approximately 15,000 UK state pensioners from Scotland receive healthcare that is funded by the UK Government under the S1 scheme while residing in other EEA countries. In the worst case scenario of 'no deal' we would expect their state healthcare costs to continue to be met by the UK Government. In any

event, we judge it is most unlikely that they would all return to Scotland because of a healthcare funding shortfall. An unexpected influx of returning state pensioners could place certain pressures on health and social care services in some areas. However, we believe that our NHS and social services would have the capacity to cope with returning state pensioners, without this having an adverse impact on service provision.

On **surveillance**, I agree it is important that information about cross border risks to health continues to be shared between Scotland and EU countries. Following EU withdrawal, the UK's responsibilities under the International Health Regulations will remain, and therefore the UK will continue to send and receive alerts about serious public health issues through World Health Organisation alerting arrangements. However, I agree that it would be preferable for the UK to continue to have a close relationship with the European Centre for Disease Prevention and Control. My Officials are working closely with counterparts in Public Health England to develop mitigation options for potential impacts on health protection.

Recruitment and retention of staff across the health, research and social care professions is characterised by complex global supply and demand profiles, as the Scottish Government signalled in evidence to the Migration Advisory Committee. Notwithstanding the significant commitments and resource investment in increasing undergraduate nursing and medical training places, NHS Scotland, alongside social care providers, will continue to rely on a measure of inward migration. A responsive immigration system is essential to promoting resilience in order to ensure our public services can continue to deliver excellent care and to promote scientific excellence. Therefore, I agree with your recommendations that powers over immigration be devolved to the Scottish Parliament. Indeed, the Scottish Government has already set out proposals for how a tailored Scottish migration system might work.

The Scottish Government recognises the challenges EU withdrawal poses for the **research workforce and collaboration**. To mitigate some of these challenges, NHS Research Scotland (NRS) is working to ensure Scotland is promoted globally as a "come-to" place, attracting research and developing strategic partnerships. NRS also works closely with domestic health research funders, industry and clinical research organisations to give some of the quickest and most effective study start-up times and processes in Europe. In relation to research funding, I welcome the Committee's positive comments. The Scottish Government, together with key relevant stakeholders, will continue to ensure that partners in Europe are clear about the excellence of our research and innovation base and are in no doubt about Scotland's continuing commitment to maintaining an active role. I also fully agree that continued alignment with the clinical trials regulations is essential and that continued access to the portal and database is critical.

I agree that **mutual recognition of professional qualifications** needs to continue post-EU withdrawal. I have written to UK Ministers on a number of occasions to highlight the importance of maintaining the current system, or as close to it as possible. Continued access to the Internal Markets Information (IMI) system, as is the case with other similar systems, will be subject to the negotiated settlement. However, the importance and utility to stakeholders of IMI is well-recognised. My officials and I will continue to reiterate these points during discussions with UK counterparts, including in the context of all the various scenarios we could be faced with after withdrawal.

You raise questions in your report about what can be done post-EU withdrawal to make it easier for **postgraduate medical trainees changing specialties**, without their losing credit for work already undertaken. The issue of increasing flexibility for trainees within and between disciplines, allowing recognition of prior learning, was highlighted as needing action by the 'UK Shape of Training' Steering Group. The Group's report and recommendations

were published on 11 August 2017 and endorsed by a 4-nation Health Minister statement. Since then, work to review training curricula has commenced, with an on-going programme of work requiring all UK Medical Colleges and Faculties to review their curricula and ensure greater recognition of previously acquired medical training. The Scottish Government is satisfied that good progress is being made to address the inflexibilities within postgraduate medical training and welcomes the collaborative efforts of the GMC and Medical Colleges to work constructively in achieving the changes patients and service providers need.

In terms of **planning for EU withdrawal**, Scotland is the first nation in the UK to publish a National Health and Social Care Workforce Plan. This plan covers primary, secondary and social care and recognises the challenges that leaving the EU will present. To support this work we have established a robust workforce planning network. In terms of social care, we are working with COSLA to address recruitment and retention issues including enhancing career pathways, training and development and a campaign to promote the sector as a career destination of choice. We are also supporting improvements to workforce planning through development of more integrated data provision, guidance and tools, all of which aim to improve capacity to manage workforce demand and supply.

The Scottish Government has pressed for the UK to continue as a full member of the **European Medicines Agency**. We welcome the UK Government's recent adoption of that position and will continue to do all we can to ensure the medicines supply chain is not adversely affected by EU withdrawal. The regulation for the licensing, safety and efficacy of medicines is currently reserved and the responsibility of the Medicines and Healthcare products Regulatory Agency (MHRA), which operates on a UK-wide basis. We continue to work with the MHRA and Department of Health and Social Care to ensure that the needs of Scottish patients are fully taken into consideration. I fully agree with the Committee's conclusions with respect to medical devices: the UK must remain fully aligned to EU regulations. Finally, it is in the interest of both the UK and EU to avoid disruption in cross-border trade, especially for medical products such as the radio-isotopes critical for cancer treatment. NHS National Services Scotland is in contact with NHS colleagues in England, Wales and Northern Ireland about this issue, to ensure that pragmatic solutions are in place.

I have noted the concerns expressed by stakeholders about the risks posed if **common frameworks** are imposed on Scotland, without proper respect for the devolution settlement and the distinctive public health environment in Scotland. I also note the view that there are areas where it makes sense for there to be UK wide common frameworks, such as in respect of blood safety, organs and tissues. Furthermore, we have consistently said we are not opposed to common frameworks where these are in Scotland's interests but that they must be put in place by agreement, not imposed, and happen in a manner that respects and recognises devolution. We also acknowledged there is a role for both the Parliament and key stakeholders in considering any arrangements negotiated between the governments. I will ensure the Committee is kept updated on the progress of these discussions.

I hope that this update and response to your report is helpful. Given the many risks which your report highlights, I am now more clear than ever that the only way to protect patients, staff and health and social care services is by staying inside the EU, and failing that by retaining our membership of the Single Market and Customs Union.

Best wishes,

[redacted]

SHONA ROBISON

Health Workforce and Strategic Change Directorate
Shirley Rogers, Director

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Chief Executives

Copied to:
Chairs
HR Directors
Employee Directors
Communications Leads
Finance Directors

29 June 2018

Dear Colleagues,

OPERATIONAL READINESS FOR EU WITHDRAWAL

Following our discussion at the meeting of Chief Executives on 13 June, I am writing to request that Boards ensure that their organisations are planning for the potential impacts of EU withdrawal.

As EU withdrawal draws closer, it is in the interests of all Boards to be actively planning for the potential operational implications. You will recall that, immediately following the EU referendum, Paul Gray wrote to Chairs and Chief Executives to underline that the Scottish Government greatly values the contribution of every member of staff in NHS Scotland, regardless of citizenship. Workforce issues continue to be crucially important, given the vital contribution to the NHS made by EU27 staff. However Boards also need to be planning for the broader implications of EU withdrawal, such as potential impacts on the medicines and medical equipment supply chains. Some of these issues have been discussed at recent meetings with Chairs, HR Directors, Directors of Finance, Communications Leads and the Scottish Partnership Forum, as well as at our meeting on 13 June.

I am attaching to this letter some materials which I hope will be useful in facilitating your preparations for EU withdrawal.

Operational Readiness Checklist

To assist your work on assessing your Board's state of readiness, I am attaching at **Annex A** a checklist of questions which can be applied when considering the full range of potential impacts that could affect most Boards. I hope Boards will find this checklist useful during the course of your preparations. In terms of taking this forward, Boards should consider EU withdrawal issues alongside other factors which could potentially impact on business continuity, and make use of existing resilience planning arrangements. This template should be returned to [redacted]@gov.scot by 14 September.

I am proposing that the completed annex A returns should serve as a basis for discussions at the planned Chief Executives Development Session, which was proposed at our meeting on 13 June. This will mean that each Board's assessment of readiness will be shared amongst all Chief Executives to inform discussion at the meeting. Your returns may also be shared with colleagues within the Government

In addition, as I made clear at our meeting on 13 June, my team stands ready to provide further support to Boards going forward, including by providing regular updates to you on EU withdrawal issues. I will aim to send you the first such update by the end of July.

I had hoped to include in this letter a further questionnaire that is due to be sent to all public sector bodies in Scotland, focussing in particular on workforce implications of EU withdrawal. However, this centrally organised questionnaire has been delayed. It will likely issue soon, with a tight turnaround time. I will forward on this second questionnaire as soon as I receive it.

Guidance for EU Staff and Managers

I wrote to HR Directors on both 13 July and 22 December 2017, asking them to ensure they were being pro-active in communicating with staff about EU withdrawal-related issues and helping to signpost staff to relevant information. It is therefore disappointing that, in our recent series of meetings, we have heard little about activity underway across Boards to communicate with and support staff. Given that EU withdrawal is drawing closer, and that we now expect the UK Government to introduce its 'settled status scheme' for EU citizens' living in the UK post-Brexit in the coming months, communication with staff is now ever more urgent.

I am therefore asking Boards, as a priority, to put in place arrangements for communicating with EU staff. To help with this, I attach at **Annex B** two guidance notes – one for managers on supporting EU27 and EEA staff; and one aimed at staff themselves. This guidance includes links to further detailed material produced by the Scottish Government, the Home Office and the European Commission, which includes case studies and Q&A material. This guidance can be added to intranets, etc, and should be used alongside any other activity which Boards consider would be helpful.

Finally, I attach at **Annex C** a communication from the Home Office giving latest details of the planned EU Settlement Scheme, which we have been asked to pass on.

I look forward to further discussions with you on these issues in the coming months, including at your forthcoming development session. As before, I will ensure that you receive further updates as the Brexit negotiations progress, and that we have a further opportunity to discuss readiness later in the year.

Yours sincerely,

Shirley Rogers

Shirley Rogers
Director of Health Workforce and Strategic Change

St Andrew's House, Regent Road, Edinburgh EH1 3DG
www.gov.scot

Annex A: NHS Scotland Board Operational Readiness Checklist

Health Board:

Completed by:

Date:

(1) How ready is your Board to deal with the potential operational impacts of EU withdrawal?;	
(2) Is your Board already seeing impacts of EU withdrawal and, if so, what are you doing to mitigate these impacts?;	
(3) What risks is your Board identifying as a result of EU withdrawal, how are these being recorded and what sorts of mitigating actions are being identified to deal with them?;	
(4) What more needs to be done now to ensure operational readiness in your Board?;	
(5) What is your Board doing to ensure it has the data it needs to (a) plan for the impact of EU withdrawal on your workforce and the local services you provide; and (b) consider the future immigration status of non-UK EEA staff?;	
(6) What is your Board currently doing to communicate with and support EU27 staff?	
(7) Have you assessed the potential financial implications for your organisation arising from EU withdrawal. If so, what measures have you put in place to address these?	

Return to James.How@gov.scot by 14 September 2018

Supporting NHS Scotland staff affected by Brexit – Guidance for NHS Scotland Line Managers

Introduction

This guidance note has been prepared to help managers provide support to members of staff from the European Union (EU)/European Economic Area (EEA) and Switzerland and their families, as we approach Brexit.

Following the EU referendum result in June 2016, the Director-General Health and Social Care and Chief Executive of NHS Scotland, Paul Gray, wrote to all NHS Scotland Boards, emphasising the value he places on all staff, regardless of nationality. He followed this up with a further letter, in July 2017, in which he drew attention to information and guidance being made available on the Scottish Government website.

As the UK moves towards leaving the EU, we **[insert organisation)** are committed to supporting all staff affected by Brexit. We are therefore providing this guidance to managers so that they can support EU/EEA staff and those affected by the Brexit vote.

We will provide further updates and clarity as Brexit discussions progress.

1. Keeping up-to-date

NHS Scotland staff can keep up-to-date with developments around the UK-EU negotiations and EU citizens' rights by:

- visiting the Scottish Government's website on citizen's rights: https://beta.gov.scot/publications/position-eu-citizens-rights/
- signing up for email alerts from the Home Office on citizens' rights: https://www.gov.uk/guidance/status-of-eu-nationals-in-the-uk-what-you-need-to-know
- visiting the European Commission's website on citizen's rights: https://ec.europa.eu/unitedkingdom/services/your-rights/Brexit_en

2. Managing NHS Scotland colleagues concerned about Brexit

The outcome of the referendum on the United Kingdom's membership of the European Union is about to change the status of all non-UK EU/EEA nationals living in the UK. This has caused significant concern and distress for a considerable number of NHS Scotland staff who are directly or indirectly affected by these changes.

As a manager, you may be working with a colleague who has been affected by the EU Referendum outcome, for example:

- a non-UK EU/EEA country citizen

- a dual citizen
- an Irish, Maltese or Cypriot citizen who has a different status to other EU citizens in the UK
- a UK citizen who has close family members holding EU/EEA citizenship
- a non-UK, non-EEA citizen who is the family member of an EU/EEA citizen

Given the multitude of personal and family circumstances, you should take into account that Brexit may present different challenges or concerns for your colleagues.

How to provide support

Managers should provide appropriate support using empathy and understanding. Regular conversations between managers and staff are an opportunity to have honest and open conversations about the impact Brexit is having on them. Staff members affected by Brexit can use this time to raise any issues that they think you should be aware of and, if appropriate, address in the context of the workplace.

Processes around the EU exit settlement scheme, citizenship or immigration may be stressful and onerous for colleagues and their partners and dependants. In line with the general approach set out in the national 'Supporting the Work Life Balance PIN policy', managers are encouraged to take a flexible and facilitative approach in responding positively to reasonable requests from EU/EEA nationals for either annual leave or flexible working to deal with the bureaucratic elements of Brexit.

3. Right to live and work in the UK - key terms

EU/EEA national colleagues obtain their right to reside/work in the UK from EU law. The UK's withdrawal from the European Union raises concerns for EU/EEA nationals because EU law will no longer apply to the UK. Many EU/EEA nationals colleagues are taking a number of steps to secure their status in the UK.

Below is an explanation of some of the key terms EU/EEA nationals may use when discussing their status:

Permanent residency

EU/EEA nationals qualify for permanent residence after five years of living in the UK - subject to meeting certain conditions. Permanent residence gives them the right to live permanently in the UK, but can be lost if they are absent from the country for over two years.

EU Exit Settlement Scheme or 'Settled Status'

During withdrawal negotiations, the UK and EU27 agreed a joint technical note on citizens' rights at negotiator level, reaching consensus on a number of areas. The UK plans to introduce a new settlement scheme. EU citizens and their family members wanting to remain in the UK will have to apply to get their status regularised.

It is expected that the settlement scheme process will be more user-friendly than existing processes for residence under EU law, however the scheme is not yet open.

The Home Office plans to open the application process for the settlement scheme on a voluntary basis from the second half of this year, before it becomes mandatory in January 2021. Our understanding is that individuals will need to engage with the settlement scheme before 30 June 2021 if they want to retain their rights and remain in the UK – even if they already have permanent residence. The latest guidance from the Home Office is at: https://www.gov.uk/government/news/home-office-publishes-details-of-settlement-scheme-for-eu-citizens

Naturalisation

After obtaining permanent residency, applicants can apply to naturalise as British citizens. This requires applicants to sit the Life in the UK Test and pass a language test, as well as collecting some documentation.

Making a residency or citizenship application can be long and time-consuming, with individuals needing to take time off to sit a test, travel to other cities (or countries) to collect documents, or attend legal appointments. There are financial implications to consider when making an application which can cause worries to members of staff and their families. For example a naturalisation application costs in excess of £1000.

4. Settled status costs and documentation

The Scottish Government has committed to look to meet the cost of applying for settled status for EU citizens working in the Scottish devolved public sector. Whilst the Scottish Government's powers in relation to immigration are limited by the current constitutional arrangements, it can seek to support EU nationals working within our public services and [**insert organisation**] as your employer will liaise with the Scottish Government and advise in due course how this will work.

The Home Office published a statement of intent in relation to the EU Settlement Scheme on 21 June. This sets out some further details of the application process, which is designed to be simple. The settled status fee will cost less than the fee for a British passport - £65 and £32.50 for children under 16. Moreover, for those who already have valid permanent residence or indefinite leave to remain documentation, they will be able to exchange it for free. There will be support for the vulnerable and those without access to a computer and there will be no quotas for applications. The statement advises people that they do not need to do anything just yet. The scheme will open later this year and be fully operational by 30 March 2019. The deadline for applications will be 30 June 2021.

Handling documentation requests

We will endeavour to have procedures in place in time to provide staff with the documentation they need to support any permanent residency or citizenship applications. Staff should make requests for documentation directly to their Board's HR Department.

Support for EU and EEA nationals – Guidance for NHS Scotland Staff

1. Support for NHS staff affected by Brexit

This guidance note has been prepared to provide advice to members of staff from the European Union (EU)/European Economic Area (EEA) and Switzerland and their families, as we approach Brexit.

Following the EU referendum result in June 2016, the Director-General Health and Social Care and Chief Executive of NHS Scotland, Paul Gray, wrote to all NHS Scotland Boards, emphasising the value he places on all staff, regardless of nationality. He followed this up with a further letter, in July 2017, in which he drew attention to information and guidance being made available on the Scottish Government website.

As the UK moves towards leaving the EU, we **[insert organisation)** are committed to supporting all staff affected by Brexit. We are therefore providing this guidance to help EU/EEA staff and those affected by the Brexit vote.

We will provide further updates and clarity as Brexit discussions progress.

2. Keeping up-to-date

NHS staff can keep up-to-date with developments around the UK-EU negotiations and EU citizens' rights by:

- visiting the Scottish Government's website on citizen's rights: https://beta.gov.scot/publications/position-eu-citizens-rights/
- signing up for email alerts from the Home Office on citizens' rights: https://www.gov.uk/guidance/status-of-eu-nationals-in-the-uk-what-you-need-to-know
- visiting the European Commission's website on citizen's rights: https://ec.europa.eu/unitedkingdom/services/your-rights/Brexit_en

3. NHS Scotland staff concerned about Brexit

The outcome of the referendum on the United Kingdom's membership of the European Union is about to change the status of all non-UK EU/EEA nationals living in the UK. This has caused significant concern and distress for a considerable number of NHS staff who are directly or indirectly affected by these changes.

You may be affected by the EU Referendum outcome, for example because you are:

- a non-UK EU/EEA country citizen
- a dual citizen
- an Irish, Maltese or Cypriot citizen who has a different status to other EU citizens in the UK
- a UK citizen who has close family members holding EU/EEA citizenship

- a non-UK, non-EU/EEA citizen who is the family member of an EU/EEA citizen

Given the multitude of personal and family circumstances, Brexit may present you with a range of different challenges or concerns.

Accessing support

In the first place, you should look to your manager to provide appropriate support, empathy and understanding. Regular conversations with your manager are an opportunity to have honest and open conversations about the impact Brexit is having on you. Staff members affected by Brexit can use this time to raise any issues you think your manager should be aware of and, if appropriate, look for ways to address these issues in the context of the workplace.

Processes around the EU Exit settlement scheme, citizenship or immigration may be stressful and onerous for EU and EEA staff and their partners and dependants. In line with the general approach set out in the national Supporting the Work Life Balance PIN policy, your manager has been encouraged to take a flexible and facilitative approach in responding to reasonable requests for either annual leave or flexible working to deal with the bureaucratic elements of Brexit.

4. Right to live and work in the UK - key terms

EU/EEA national staff obtain their right to reside/work in the UK from EU law. The UK's withdrawal from the European Union understandably raises concerns for EU/EEA nationals because EU law will no longer apply to the UK. We are aware that many EU/EEA nationals colleagues are taking a number of steps to secure their status in the UK.

Below is an explanation of some of the key terms you may need to use when discussing your status:

Permanent residency

EU/EEA nationals qualify for permanent residence after five years of living in the UK - subject to meeting certain conditions. Permanent residence gives them the right to live permanently in the UK, but can be lost if they are absent from the country for over two years.

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It is expected that the settlement scheme process will be more user-friendly than existing processes for residence under EU law, however the scheme is not yet open.

The Home Office plans to open the application process for settled status on a voluntary basis from the second half of this year, before it becomes mandatory in January 2021. Our understanding is that individuals will need to engage with the settlement scheme before 30 June 2021 if they want to retain their rights and remain in the UK – even if they already have permanent residence. The latest guidance from the Home Office is at: https://www.gov.uk/government/news/home-office-publishes-details-of-settlement-scheme-for-eu-citizens

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The Scottish Government has committed to look to meet the cost of applying for settled status for EU citizens working in the Scottish devolved public sector. Whilst the Scottish Government's powers in relation to immigration are limited by the current constitutional arrangements, it can seek to support EU nationals working within our public services and **[insert organisation]** as your employer will liaise with the Scottish Government and advise in due course how this will work.

The Home Office published a statement of intent in relation to the EU Settlement Scheme on 21 June. This sets out some further details of the application process, which is designed to be simple. The settled status fee will cost less than the fee for a British passport - £65 and £32.50 for children under 16. Moreover, for those who already have valid permanent residence or indefinite leave to remain documentation, they will be able to exchange it for free. There will be support for the vulnerable and those without access to a computer and there will be no quotas for applications. The statement advises people that they do not need to do anything just yet. The scheme will open later this year and be fully operational by 30 March 2019. The deadline for applications will be 30 June 2021.

6. Handling documentation requests

NHS Scotland will endeavour to have procedures in place in time to provide staff with the documentation they need to support any permanent residency or citizenship applications. Staff should make requests for documentation directly to HR Departments within their Boards.

Annex C

Home Office

Dear Chief Executive,

The UK Government has published more details about the new scheme for EU citizens and their families, to allow them to continue living and working here as now after the UK leaves the EU. This is an important step in delivering the reciprocal agreement with the EU, which also guarantees the rights of UK nationals living in the EU.

The agreement recognises the valuable contribution that EU citizens make to the UK, and that UK nationals make to the EU. We want EU citizens and their families who have made the UK their home to stay, and the process we are setting up will mean they can do so quickly and easily.

A simple and straightforward scheme will be phased in later this year, and will gradually open more widely until its full launch by the end of March 2019, to enable EU citizens arriving before the end of 2020 to apply for their status. Yesterday's publication includes the draft Rules for the scheme, as well as confirming that:

- Applications will be via a short online process.
- Most EU citizens will only need to prove their identity and demonstrate their residence in the UK. They will be required to declare whether they have any criminal convictions and we will check that they are not a serious or persistent criminal.
- It will cost £65 and £32.50 for children under 16.
- It will be free for those with valid documented permanent residence or valid indefinite leave to remain or enter.

A range of user-friendly guidance and support, including a customer contact centre, will be in place when the scheme launches to help citizens through the process, and we are taking particular care that adequate support is in place for more vulnerable citizens.

The Immigration Rules for the scheme will be formally laid before Parliament later this summer and we will, meanwhile, continue to engage with stakeholders, including employers, local authority representatives and community groups, about the detailed design of the scheme.

You can read more about the scheme at GOV.UK. Also, look out for communications tools which employers, service providers and networks can use to help keep EU citizens informed. We will be in touch with further information about this soon.

EU citizens and their family members do not need to do anything now. There will be no change to their current rights until the end of the implementation period on 31 December 2020, and the deadline for applications to the scheme for those resident here by the end of 2020 will be 30 June 2021.

Annex C

We greatly appreciate your continued support in communicating about the scheme and providing reassurance to EU citizens. Please encourage EU citizens in your organisation and networks to visit GOV.UK and sign up to the UK Government email list to receive regular updates.

Yours sincerely,

Home Secretary

Cabinet Secretary for Health and Sport
Shona Robison MSP

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Mr Jeremy Hunt MP
Secretary of State for Health
Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS

24 July 2017

Dear Jeremy

I am writing to seek an update on the UK Government's plans in relation to the UK's membership of the European Medicines Agency (EMA) and clarity on the future relationship between the Medicines & Healthcare products Regulatory Agency (MHRA) and the EMA.

I noted your letter to the Financial Times on 4 July where you stated the UK Government's commitment to continued close working and collaboration with the EU in the interests of public health and safety. It is the Scottish Government's view that the best way to secure this outcome is for the UK to remain within the EMA. You appeared to rule that option out when you spoke at the House of Commons Health Committee on 24 January 2017, however your letter to the Financial Times suggested that a continued relationship may now be a possibility. It is essential that clarity on the UK Government's position is provided as soon as possible.

To date, the UK Government has been unable to provide any information regarding the timescales for decision-making on this issue or detail on the process for the negotiations. In addition, there has been little engagement with the Scottish Government about the future shape of medicine regulation or the relationship between the medical licensing agencies. It is a clear risk that pharmaceutical companies could be less attracted to the UK market as a priority than they will be to the larger combined states of the EU and US. This could result in potential delays to patients getting access to the medicines they need in Scotland and the wider UK. We are also concerned that 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 as a result. To add to this, there are questions over clinical trials and pharmacovigilance for medicines and a risk of this impacting on both access to new medicines and medicines safety. For these reasons I am deeply concerned by the possibility of the UK no longer participating in the EMA.

The Scottish Government is clear that all possible options must be considered as quickly as possible and appropriate plans put in place which will ensure that medicines licensed through the EMA remain approved for use across the UK, whatever the future relationship with the EU may be.

I would be grateful for an update on the UK Government's position and, as we move forward, would welcome the full and regular involvement of the Scottish Government in these crucial discussions and decisions.

SHONA ROBISON

Cabinet Secretary for Health and Sport
Shona Robison MSP

Minister for UK Negotiations on Scotland's Place in Europe
Michael Russell MSP

Scottish Government
Riaghaltas na h-Alba
gov.scot

Dr Sarah Wollaston MP
Chair, Health Select Committee
SUBMITTED ONLINE

26 October 2017

Dear Chair

Thank you for the opportunity to contribute to the Health Select Committee's inquiry into 'Brexit – medicines, medical devices and substances of human origin'.

The Scottish Government's long-standing policy and commitment has been to retain membership of the European Union. That remains our position and reflects the way the Scottish people voted in the 2016 EU referendum. For those reasons we will also continue to seek to protect Scotland's interests and work to keep Scotland in the EU Single Market and a Customs Union.

The Scottish Government's view, detailed within this submission to the Committee, is that our ability to continue to operate or participate within the range of relevant EU frameworks and legislation would be in the best interests of the whole of the United Kingdom through continued cross-border working and facilitation of an on-going European single market in a range of areas. We have significant concerns that a failure to do so could have a damaging impact on patient health and safety as well as a number of industry sectors throughout the UK due to a range of factors that are set out in this paper.

Answers to the specific questions put by the Committee are set out within this document.

SHONA ROBISON **MICHAEL RUSSELL**

St Andrew's House, Regent Road, Edinburgh EH1 3DG
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Scottish Government Response to House of Commons Health Select Committee Inquiry: 'Brexit – medicines, medical devices and substances of human origin'

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?

Following the UK's withdrawal from the EU, what alternative arrangements for the regulation of medicines, medical devices, medical products and substances of human origin could be introduced? What are the respective opportunities, risks and trade-offs involved?

For the Scottish Government, the ability to continue to operate or participate within the range of relevant EU frameworks and legislation would be in the best interests of the UK through continued cross-border working and facilitation of an on-going European single market in a range of areas.

In our view, the best way to meet the UK Government's stated commitment of continued close working and collaboration with the EU in the interests of public health and safety is for the UK to remain within the European Medicines Agency (EMA) and to continue to secure access to the EU Clinical Trials Portal. Withdrawing from the EMA is highly likely to be detrimental to patients. It is a clear risk that pharmaceutical companies could be less attracted to the UK market as a priority than they will be to the larger combined states of the EU and US, potentially resulting in delays to patients getting access to the medicines they need. We are also concerned that 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. The Cabinet Secretary for Health and Sport, Shona Robison, has written to the Secretary of State for Health, Jeremy Hunt, urging him to secure the UK's continued place within the EMA.

Our continued involvement in the licensing and medicines safety arrangements through the EMA is crucial in maintaining access to medicines and will help to secure and sustain the supply of essential medicines throughout the UK supply chain. Despite the UK Government's assurances we are already beginning to experience some early economic consequences of the UK's proposed withdrawal from the EU, particularly in relation to generic drugs where the major manufacturers of base active ingredients are located in the far east and imported to the EU and UK for assembly. In general terms, the trading of drugs is a global market and the strength of the pound against the US Dollar and the Euro is beginning to show signs of increasing costs of importing drugs and the active ingredients for the assembly of generics. Community pharmacy contractors are already reporting that this is having an impact on their purchasing power and the narrowing of margins which is an important part of the community funding envelope across the UK administrations.

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, including medicinal products, is within the EU's exclusive competence; the promotion of research and technological development is shared competence). Being able to continue to operate within the ambit of relevant EU clinical trials legislation, including access to supporting IT infrastructure such as the developing Clinical Trial portal, will be in the interests of continued cross-border working and facilitation of an on-going single market in medicinal products.

The new EU Medical Devices Regulations for medical devices and in-vitro medical devices were published by the European Parliament in 2017 and will be fully in force by 2020. If the UK leaves the EU in 2019, the EU Regulations may not be fully implemented, and there may be divergence between the EU and UK. This is of serious concern to the UK medical devices industry, as access to the EU market is vital. Industry is clear that it does not want to see divergence from the EU system and have written to the UK Government and EU Chief Negotiator to express their concerns.

We would wish to continue a similar regulatory approach under the Medicines and Healthcare products Regulatory Agency (MHRA), the Human Tissue Authority (HTA) and the Human Fertilisation and Embryology Authority (HFEA) 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 in order to allow for continued free movement of organs, blood, tissues, cells and gametes 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 and common procurement. 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).

The current system under the MHRA, HTA and HFEA works relatively well. We would want to keep UK and Scottish blood, organ and tissue and cells standards as close to those of the EU as possible. The same principles apply in relation to Advanced Therapy Medicinal Products (ATMPs) including gametes.

We view it as important that the free movement of healthcare professionals (including pharmacists and transplant surgeons) is retained and that cross-border recognition of professional qualifications, education and training continues in order to support that workforce supply pipeline. Whilst professional regulation is a mix of devolved and reserved competence, Ministers have long maintained four-nation working and consistency of processes, standards and expectations for the benefit of employers, patients and professionals. To that end the Cabinet Secretary for Health and Sport has also written to Philip Dunne MP, UK Minister of State for Health, asking him to ensure that parity of minimum standards for the "sectoral professions" under 2005/36/EC (as amended by 20013/55/EU) is maintained regardless of the outcome of Brexit in order to continue to facilitate mutual recognition of qualifications between states.

Finally, we want to retain continued access to cross-border recognition of prescription forms particularly in consideration of those UK nationals that may continue to reside and/or work in EU member states (and *vice versa*). This arrangement currently helps to support continuity of care when moving back and forward between their state of origin and state of residence.

How much time is needed to facilitate a smooth transition to new arrangements? Is it possible, or desirable, to move directly to new arrangements post-29 March 2019, or are transitional arrangements needed?

It is likely that transitional arrangements will be needed for the UK to continue to operate with the ambit of relevant EU clinical trials legislation, including access to supporting IT infrastructure such as the developing clinical trial portal. In terms of medicines and medical devices, industry have expressed a wish to see transitional arrangements, given their concerns.

In relation to the Blood, Organ and Tissues and Cells Directives, these are already transposed into UK law, however the EU Pharmaceutical regulations (EudraLex) and the Advanced Therapy Medicinal Products Regulations (ATMP) will need to be transposed. ATMPs are currently subject to EU-level review and Marketing Authorisation through the European Medicines Agency (EMA). This work will need to be carried out by the MHRA and the Commission on Human Medicines (CHM) following EU withdrawal, which will require an expansion in resources, including replicating existing expert European assessments and advisory committees, such as the Committee on Advanced Therapies. Therefore a significant transitional period may be needed to replicate the EMA's processes and procedures within the UK.

How will withdrawal from the European Union affect the UK's ability to influence international standards in life sciences?

The UK currently has considerable on EU regulatory policy and standards in relation to life sciences through the MHRA. This will be lost post-Brexit, although the UK and Scotland can continue to influence international standards through the Pharmaceutical Inspection Co-operation Scheme.

UK-based companies wish to know if the UK Government will continue with the CE (Conformité Européene) standard or adopt the FDA (US Food and Drug Administration) standard. The evidence from industry, and the effectiveness of the EU system, suggests that the CE standard is the preferred option for UK businesses, however the detail of which system –old or new- for the UK is unknown at present and will be part of future negotiations with the EU.

In general terms there is usually a one to three-year delay in launching new medical devices into general clinical practice in the US compared to the EU. This is partly because the regulatory process in Europe is considered to be less bureaucratic, more efficient, and more predictable than in the US. Another reason is that the FDA requires evidence of both safety and efficacy of a device, whereas a European CE Mark only requires proof of safety and that the device performs in a manner consistent with the manufacturer's intended use.

The UK Government have yet to confirm whether the legal requirements associated with CE marking are ones we will retain for products sold in the UK, however the Institution of Mechanical Engineers published *'Medical Devices and CE Marking: The Impact of Brexit'* which outlined their concerns if the UK Government chooses not harmonise with EU regulation on medical devices, saying that "it is vital to maintain continuity with the EU CE certification processes and enable UK manufacturers to export medical devices into the 100bn euro European Med Tech Market".

The Institution made three key recommendations:

1. The UK Government negotiates a Med Tech compliancy arrangement with the EU to ensure continuity in the CE marking process for UK manufacturers. This arrangement should be supported by parallel policies to encourage long-term investment in the sector. The goal is to attract Med Tech SMEs to the UK through clear support for innovation and product development.

2. UK industry and the NHS should work together to ensure that they retain influence over future European regulation.

3. UK Research and Innovation must address the EU funding short-fall. They must take the opportunity to remove the current imbalance in support between early-stage start-ups and large established companies.

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 EU medical device regulatory framework will only be fully endorsed by 2020 and in 2022 for in-vitro medical devices. The need for patients to have access to the full range of enhanced patient safety features in the new Regulations is vital so Scotland must remain a full partner. The ability of Scotland's large number of small and medium sized enterprises to reach into this vital market on the same status is important for their continued growth.

Medical devices require multiple components and quality checking in many different EU countries. To do this work requires rare professional skills which must be maintained if Scotland is to continue to provide high quality care and economic growth.

The Scottish Government is also 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 international research collaboration in important areas, such as developing regenerative medicine techniques to address some of the most pressing health threats and challenges. 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 prone to investing 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, with the UK at a later date if at all. Such a scenario would threaten the timely patient access to new medicines we currently enjoy as a member of the EMA.

Withdrawal from the EU 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. 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 not being fully engaged. Conversely, EU researchers/research organisation 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 EU. Non-EU collaborations may be largely unaffected, however there is a risk that diminished international competitiveness and influence of the Scottish and UK health research sector and exclusion from collaborative networks with the EU may reduce the attraction of Scotland and the UK to potential partners outside the non-EU, including commercial partners.

Continuing to operate within the ambit of relevant EU clinical trials legislation, including access to supporting IT infrastructure such as the developing Clinical Trial portal, would mitigate some of these impacts as would the underwriting by the UK Government of current funds available under Horizon 2020.

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.

Scottish Government
October 2017

Document 21 - Annex from Brief

- EU 27 nationals make up 5.0% of the Scottish workforce in employment across sectors, and account for 3.5% (13,000) of the workforce in the Health and Social Care Sector (Annual Population Survey 2016, Office for National Statistics)
- Just over 1,177 non-UK EEA-qualified doctors in Scotland, from a total of 21,609 – 5.9%. (GMC 2017)
- The free movement of people and the mutual recognition of qualifications allows skilled and experienced health professionals from the EU/EEA to work in our NHS. Without this, our ability to continue to provide high-quality health and social care services for the people of Scotland will suffer, particularly in Scotland's remote and rural communities.
- The impact of Brexit on the Health and Social Care workforce will depend on the precise form of withdrawal from the EU. Existing professional registrations will remain in place, with immigration arrangements likely to become the primary barrier to access. Continued uncertainty will have an impact on our ability to continue to attract non-UK EU nationals to work and live in Scotland.
- In addition to workforce issues, Brexit also raises concerns in areas such as the medicines supply chain, medical devices and clinical trials, access to future EU funding and the rights of Scottish citizens to access state-provided healthcare across the EU.

TOP LINES

- 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, we are working to see that their rights and place in our nation are protected.

- We are extremely concerned at the impact of leaving the EU, and in particular of ending the freedom of movement on the workforce in Scotland. We need to retain our ability to recruit staff from inside and outside EU. Cross-border mobility and freedom of movement are essential for our health and social care services.

- 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.

- 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).

- Estimates from the Annual Population Survey show that in 2016 EU27 nationals make up approximately 5.0% of the overall Scottish workforce, with around 4.4% of the workers in the social services sector being EU27 nationals (breakdown not available for Health sector). Work to address the NHS

workforce data issue is underway with NHS Boards and we have commissioned work to help improve our understanding of the contribution of EU27 nationals to the social services workforce.

Nursing and Midwifery Council (NMC) Report Register Report (published 2 Nov)

- We are aware of the figures published by the NMC showing the continuing decline in the overall number of nurses and midwives on their register, this figure having peaked in 2016.
- Nurses and midwives from the EEA make up around 5% of the register across the UK and **all healthcare employers, including NHS Scotland, are concerned at the sharp decrease in the number of EEA nationals joining the register** in the year to September.

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.

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.

Health

- The free movement of people and the mutual recognition of qualifications allow skilled and experienced health professionals from the EU/EEA to work in our NHS. Without this, our ability to continue to provide high-quality health and social care services for the people of Scotland will suffer particularly in Scotland's remote and rural communities.
- The free movement of people within the EU has also enabled Scotland's medical schools to attract students to study medicine and dentistry. At present, EU students enjoy free tuition fees, which has made Scottish medical and dental schools more attractive to EU students.
- EU 27 nationals make up 5.0% of the Scottish workforce in employment across sectors, and account for 3.5% (13,000) of the workforce in the Health and Social Care Sector (Annual Population Survey 2016, Office for National Statistics)
- Just over 1,177 non-UK EEA-qualified doctors in Scotland, from a total of 21,609 – 5.9%. (GMC 2017)
- Around 4% of nurses and midwives and 2% of dentists in training are from the EU. (Office for National Statistics data – 29 June 2016).