Dear Chief Executive

The Health and Sport Committee has received a letter from Joe FitzPatrick, Minister for Public Health, Sport and Wellbeing (see Annexe A) containing notification on its intent to consent to UK Ministers making regulations on its behalf in relation to the following:

- The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations
- The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations
- Blood Safety and Quality (Amendment) (EU Exit) Regulations

The Committee is considering this notification from the Scottish Government and will decide if it is content that the Scottish Government give consent to UK Ministers to make regulations on its behalf in relation to the three areas detailed above.

To inform the Committee’s consideration given the MHRA's responsibility for the requirements that apply under the UK’s Blood Safety and Quality Regulations we are writing to you to seek your views and comments on the proposals.

10 October 2018
The Committee has also issued similar correspondence to the Human Tissue Authority, NHS Blood and Transplant, Scottish National Blood Transfusion Service and the Anthony Nolan Trust.

The Committee is particularly interested in whether the MHRA consider the approach being proposed with these regulations will create any barriers of access to blood.

We note some of the provisions within these regulations are expected to confer existing European Commission powers on the UK and devolved administration Ministers (in the form of power to make regulations). Operationally are there matters to be covered by these regulations you think it would be appropriate to come to Scotland rather than be dealt with at a UK level?

It would also be helpful if you could confirm whether the MHRA has been consulted by the UK or Scottish administrations on these proposals.

The Committee has a tight timescale for consideration of the notification from the Scottish Government. It would therefore be much appreciated if a response could be provided by Tuesday 16 October.

Yours sincerely

Lewis Macdonald
Convener, Health and Sport Committee
Dear Lewis

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations, the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations and the Blood Safety and Quality (Amendment) (EU Exit) Regulations

EU EXIT LEGISLATION – PROTOCOL WITH SCOTTISH PARLIAMENT

I am writing in relation to the protocol on obtaining the approval of the Scottish Parliament to the exercise of powers by UK Ministers under the European Union (Withdrawal) Act 2018 in relation to proposals within the legislative competence of the Scottish Parliament.

As you know, Mike Russell wrote to the Conveners of the Finance & Constitution and Delegated Powers and Legislative Reform Committees on 11 September setting out the Scottish Government’s views on EU withdrawal. That letter also said that we must respond to the UK Government’s preparations for a No-Deal scenario as best we can, despite the inevitable widespread damage and disruption that would cause. It is our unwelcome responsibility to ensure that devolved law continues to function on and after EU withdrawal.

I attach a notification which sets out the details of three health-related SIs which the UK Government proposes to make and the reasons why I am content that Scottish devolved matters are to be included in these SIs.

The policy rationale for the proposed changes which these SIs will make is to contribute to the continuation following EU exit of an effective regulatory regime for ensuring the safety and quality of donated human organs, tissues and cells and blood where these are intended for human transplantation or transfusion. We have not yet seen final versions of these SIs, but, based on the discussions so far with the Department of Health and Social Care and in the interests of ensuring that you have the agreed 28 days to consider this notification, we have provided the notification based on our understanding of what we expect to be included.
in the final SIs. I will of course update you once the final SIs have been laid in the UK Parliament and confirm that the significant details are as set out in this notification.

I am copying this letter to the Convener of the Delegated Powers and Law Reform Committee.

I look forward to hearing from you within 28 days from the date of this letter.

JOE FITZPATRICK
NOTIFICATION TO THE SCOTTISH PARLIAMENT

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations

A brief explanation of law that the proposals amend

These Regulations amend the UK-wide Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the 2007 Regulations), which implement a number of Directives on ensuring the quality and safety of donated human tissues and cells. The main Directive which applies in this area is Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, but there are also a number of accompanying technical Commission Directives which set out additional requirements. These Regulations also make some amendments to the Human Tissue Act 2004. Please note that these Regulations deal with tissue (such as bone, eyes, heart valves, tendons, etc.) and stem cells which are donated for transplantation.

Summary of the proposals and how these correct deficiencies

These amending regulations are largely technical in nature. They amend various provisions and definitions, in particular to treat imports of tissues and cells from EU member states or European Economic Area (EEA) states in the same way as imports from non-EU states. They also remove the requirement for tissue establishments to use the Single European Code coding system in future.

In addition, the Regulations confer some existing European Commission functions to Ministers. Firstly, Ministers will be able to bring forward Regulations regarding procedures for ensuring the traceability of exported tissues and cells and regarding certain technical requirements to ensure the safety of donated tissues and cells. In relation to Scotland, the SI is expected to enable these Regulations to be made either by Scottish Ministers or by UK Ministers on behalf of Scotland where Scottish Ministers consent to this. Secondly, the Human Tissue Authority (HTA) will be able to give directions to tissues or cells licence holders to ensure that all imports of tissue and cells intended for human application meet standards of quality and safety equivalent to those provided for in these Regulations.

An explanation of why the change is considered necessary

These changes are drafted on the basis of no deal being reached between the UK and the EU regarding continued formal cooperation in the area of Tissues and Cells. Therefore they assume that EU and EEA states will become ‘third countries’ for the purpose of imports of tissues and cells into the UK. The provisions in these Regulations do still enable UK tissue establishments to import tissues and cells from the EU and EEA as long as equivalent standards to those in the 2007 Regulations are met. If there is some form of deal, some of these provisions may be altered, depending on the terms of any deal.
Scottish Government categorisation of significance of proposals

The Scottish Government considers these proposals fall within category B. Whilst many of the provisions in the draft Regulations are within category A because they are minor and technical in detail and focus on ensuring continuity of law, as noted above some are expected to confer existing European Commission powers to UK and devolved administration Ministers (in the form of making regulations).

Impact on devolved areas

The contents of these Regulations cover devolved policy areas. However, there is not expected to be any significant direct impact on Scotland of these legislative proposals. The provisions which confer direction-making powers on the HTA are the mechanism by which certain requirements, such as information requirements for imports, may be put in place, and not directly through the regulations. The existing requirements regarding the quality and safety of tissues and cells will remain unchanged as a result of these Regulations. Tissue is hardly ever imported to or exported from Scotland to other EU or EEA states. Whilst stem cells are occasionally imported and exported, particular procedures are already in place in the existing 2007 Regulations (as amended), which govern these one-off imports; these provisions minimise the level of information which needs to be provided in each case.

Summary of stakeholder engagement/consultation

There has been limited stakeholder engagement and consultation on these Regulations as they are technical in nature and are not expected to impact directly on stakeholders. The Scottish Government has had general discussions with the Scottish National Blood Transfusion Service (SNBTS) regarding the proposals and they are content with the proposal that Regulation should continue to be on a UK-wide basis. We also understand that the HTA will be issuing guidance to all UK tissue establishments and working with those in other parts of the UK who do import or export tissues or cells to ensure they have appropriate arrangements in place. We are working closely with UK Government counterparts to ensure that Scottish stakeholders are kept up to date.

A note of other impact assessments (if available)

The UK Department of Health and Social Care has not carried out an impact assessment in relation to these Regulations as they are technical in nature and not expected to impact on tissue establishments or other stakeholders. Whilst the legislation will change slightly regarding imports and exports to and from EU and EEA states, this is not expected to have any significant impact on tissue establishments.

Summary of reasons for Scottish Ministers proposing to consent to UK Ministers legislation

The 2007 Regulations already operate on a UK-wide basis and amendments to these have always been made by the UK Department of Health and Social Care with the agreement of the Scottish Government. Tissue and cells often move around the UK and the HTA regulates tissues and cells providers across the UK. NHS Blood and Transplant provides some tissue services in Scotland (currently e.g. for eyes and support for heart valves where patients are also an organ donor). While some tissue (e.g. tendons and heart valves) is normally retrieved and processed by SNBTS, there is close working between NHSBT and SNBTS and adherence to common standards. In addition, for stem cells, the Anthony Nolan Trust (a UK-wide charity) helps find donors for patients needing a stem cell transplant;
donors are often found in other parts of the UK or abroad. Therefore, there is a strong argument for retaining consistent regulations across the UK to ensure ease of movement of tissue and cells between Scotland and the rest of the UK.

**Intended laying date (if known) of SI/SIs**

We understand that the UK Government intent is to lay this SI in the week commencing 19 November 2018.

**If the Scottish Parliament will not have 28 days to scrutinise Scottish Minister's proposal to consent, why not?**

Not applicable.

**Information about any time dependency associated with the proposal**

There are no particular time dependencies, although in the event of no deal being reached with the EU, the UK Government will want to ensure these Regulations are in force prior to EU exit. The proposed November laying date aims to allow the Human Tissue Authority sufficient time to provide guidance and ensure that all tissue establishments which import or export tissue to or from EU and EEA states have time to ensure they have the appropriate arrangements in place with partners in these states.

**Any significant financial implications**

These Regulations are not expected to have any financial implications for stakeholders in Scotland.

**The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations**

**A brief explanation of law that the proposals amend**

These Regulations amend the UK-wide Quality and Safety of Organs Intended for Transplantation Regulations 2012 (the 2012 Regulations), which implement Directive 2010/53/EU on standards of quality and safety of human organs intended for transplantation. They also make some amendments to the Human Tissue Act 2004 and to the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

**Summary of the proposals and how these correct deficiencies**

These amending regulations are largely technical in nature. They amend various provisions and definitions, in particular to treat imports of organs from EU member states or European Economic Area (EEA) states in the same way as non-EU or EEA states.

In addition, the Regulations may confer equivalent powers to some existing European Commission powers to make regulations on Ministers. In relation to Scotland, the SI is expected to enable any Regulations to be made either by Scottish Ministers or by UK Ministers on behalf of Scotland where Scottish Ministers consent to this.
An explanation of why the change is considered necessary

These changes are drafted on the basis of no deal being reached between the UK and the EU regarding continued formal cooperation in the area of Organs. Therefore they assume that EU and EEA states will become ‘third countries’ for the purpose of imports of organs to the UK. The provisions in these Regulations do still enable organs to be imported to the UK. If there is some form of deal, some of these provisions may be altered, depending on the terms of any deal.

Scottish Government categorisation of significance of proposals

The Scottish Government feels these proposals fall within category B. Whilst most of the provisions in the draft Regulations are within category A because they are minor and technical in detail and focus on ensuring continuity of law, as noted above some are expected to confer existing European Commission powers to UK and devolved administration Ministers (in the form of making regulations).

Impact on devolved areas

The contents of these Regulations cover devolved policy areas. However, there is not expected to be any significant direct impact on Scotland of these legislative proposals. The existing requirements regarding the quality and safety of organs will remain unchanged as a result of these Regulations. While organs regularly move around the UK, they are very rarely imported to or exported from Scotland to other EU or EEA states.

Summary of stakeholder engagement/consultation

There has been limited stakeholder engagement and consultation on these Regulations as they are technical in nature and are not expected to impact directly on stakeholders. The Department for Health and Social Care has had discussions with NHS Blood and Transplant (NHSBT) regarding the proposals.

A note of other impact assessments (if available)

The UK Department of Health and Social Care has not carried out an impact assessment in relation to these Regulations as they are technical in nature and not expected to impact on NHSBT or other stakeholders who are licenced to retrieve, store or transplant organs under the 2012 Regulations. Whilst the legislation will change slightly regarding imports and exports to and from EU and EEA states, this is not expected to have any significant impact on NHSBT or other stakeholders. We understand that NHSBT will seek to put in place appropriate agreements with relevant EU member state authorities to allow the organs to continue to be shared with those countries where appropriate.

Summary of reasons for Scottish Ministers proposing to consent to UK Ministers legislation

The 2012 Regulations already operate on a UK-wide basis. Organs are allocated on a UK-wide basis and often move around the UK and the Human Tissue Authority (HTA) regulates NHSBT and all NHS bodies across the UK who are involved in the retrieval or transplantation of organs. NHS Blood and Transplant manages donation and organ retrieval across the UK. Therefore, there is a strong argument for retaining consistent regulations
across the UK to ensure ease of movement of organs between Scotland and the rest of the UK.

**Intended laying date (if known) of SI/SIs**

We understand that the UK Government intent is to lay this SI in the week commencing 19 November 2018.

If the Scottish Parliament will not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?

Not applicable.

**Information about any time dependency associated with the proposal**

There are no particular time dependencies, although in the event of no deal being reached with the EU, the UK Government will want to ensure these Regulations are in force prior to EU exit.

**Any significant financial implications**

These Regulations are not expected to have any financial implications for stakeholders in Scotland.

**Blood Safety and Quality (Amendment) (EU Exit) Regulations**

**A brief explanation of law that the proposals amend**

These Regulations amend the UK-wide Blood Safety and Quality Regulations (the 2005 Regulations), which implement Directives on ensuring the quality and safety of donated blood and blood components where these are intended for human transfusion.

**Summary of the proposals and how these correct deficiencies**

These amending regulations are largely technical in nature. They amend various provisions and definitions, in particular to treat the import and export of blood or products derived from blood components from or to EU member states or European Economic Area (EEA) states in the same way as non-EU or EEA states.

In addition, the Regulations enable the Secretary of State for Health to bring forward Regulations to set out standards in the following areas: autologous transfusions (where the donor and the recipient of the blood are the same person), quality management systems, quality and safety for the collection, testing, processing, storage and distribution of blood and blood components. In relation to Scotland, the SI is expected to enable these Regulations to be made in relation to devolved matters either by Scottish Ministers or by UK Ministers on behalf of Scotland where Scottish Ministers consent to this
An explanation of why the change is considered necessary

These changes are drafted on the basis of no deal being reached between the UK and the EU regarding continued formal cooperation in the area of blood safety. Therefore they assume that EU and EEA states will become ‘third countries’ for the purpose of imports of human blood or components of blood. The provisions in these Regulations do still enable blood to be imported from the EU and EEA. If there is some form of deal, some of these provisions may be altered, depending on the terms of any deal.

Scottish Government categorisation of significance of proposals

The Scottish Government feels these proposals fall within category B. Whilst most of the provisions in the draft Regulations are within category A because they are minor and technical in detail and focus on ensuring continuity of law, as noted above some are expected to enable the Secretary of State to make Regulations setting out standards in a number of areas.

Impact on devolved areas

These Regulations contain provisions which relate to devolved policy areas. However, there is not expected to be any significant direct impact on Scotland of these legislative proposals. The existing requirements regarding the quality and safety of blood will remain unchanged as a result of these Regulations. Some plasma is imported to Scotland from other EU states, for example some fresh frozen plasma is imported by NHS Blood and Transplant (NHSBT) in England on behalf of the Scottish National Blood Transfusion Service (SNBTS).

Summary of stakeholder engagement/consultation

There has been limited stakeholder engagement and consultation on these Regulations as they are technical in nature and are not expected to impact directly on stakeholders. The Department for Health and Social Care has had discussions with NHS Blood and Transplant (NHSBT) and the Medicines and Healthcare Products Regulatory Authority (MHRA) regarding the proposals and they seem content with them. In addition, the Scottish Government has discussed a draft of the Regulations with SNBTS; SNBTS indicated that it is content.

A note of other impact assessments (if available)

The UK Department of Health and Social Care has not carried out an impact assessment in relation to these Regulations as they are technical in nature and not expected to impact directly on blood establishments. Whilst the legislation will change slightly regarding imports and exports to and from EU and EEA states, this is not expected to have any significant impact on stakeholders.

Summary of reasons for Scottish Ministers proposing to consent to UK Ministers legislating

The 2005 Regulations already operate on a UK-wide basis. As noted above, these Regulations contain provisions covering devolved policy areas. While blood (apart from e.g. the plasma imported from EU member states by NHSBT) does not often move from other parts of the UK to or from Scotland, it does in some cases. For example, SNBTS may seek blood from NHSBT for patients with a particularly rare blood type and there are also contingency arrangements in place for NHSBT to provide blood supplies to Scotland in the Scottish Ministers, special advisers and the Permanent Secretary are covered by the terms of the Lobbying (Scotland) Act 2016. See www.lobbying.scot

St Andrew’s House, Regent Road, Edinburgh EH1 3DG
www.gov.scot
event of an emergency situation leading to SNBTS being unable to supply sufficient blood to Scottish hospitals. The four UK blood services act autonomously, although within the requirements of the 2005 Regulations; however, they do largely follow the same practices in relation to, for example, blood donor deferral criteria and the screening of blood. Therefore, there is an argument for retaining consistent regulations across the UK to ensure ease of movement of blood between Scotland and the rest of the UK.

**Intended laying date (if known) of SI/SIs**

We understand that the UK Government intent is to lay this SI in the week commencing 19 November 2018.

**If the Scottish Parliament will not have 28 days to scrutinise Scottish Minister’s proposal to consent, why not?**

Not applicable.

**Information about any time dependency associated with the proposal**

There are no particular time dependencies, although in the event of no deal being reached with the EU, the UK Government will want to ensure these Regulations are in force prior to EU exit.

**Any significant financial implications**

These Regulations are not expected to have any financial implications for stakeholders in Scotland.