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Gillian Martin, MSP
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Health, Social Care and Sport Committee
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09 December 2021

Dear Gillian

Publication of the proposed Common Frameworks for Organs, Tissues and Cells (apart from embryos and gametes), and Blood Safety and Quality.

The Minister for Public Health, Sport and Wellbeing wrote to your predecessor on 2 December 2020 with a summary of the proposed Common Frameworks for Organs, Tissues and Cells (apart from embryos and gametes) and Blood Safety and Quality.

I am writing to share the text of these provisional Frameworks with your Committee. My officials, together with their counterparts in the UK Government, Welsh Government and the Northern Ireland Executive have been working jointly to develop these Frameworks.

The provisional Frameworks were confirmed by the Joint Ministerial Committee (European Negotiations) (JMC (EN))/portfolio Ministers on 4 March 2021. I am sharing these provisional frameworks for your Committee to scrutinise.

The provisional Frameworks consist of a Framework Outline Agreement and Concordat. Please find a cover page attached which covers both frameworks, with the Framework Outline Agreement and Concordat included as separate annexes. My officials are happy to provide any further information if that would be helpful.

I am copying this letter and all attachments to Clare Adamson MSP, Convener of the Constitution, Europe, External Affairs and Culture Committee due to the Committee's interest in the overall UK Common Framework programme.

MAREE TODD

Cover page template:

1. Framework ownership

- Frameworks names:
  - Organs, Tissues and Cells Framework (apart from embryos and gametes), and
  - Blood Safety and Quality Framework
- Responsible Portfolio: Minister for Public Health, Women's Health and Sport
- Frameworks lead policy team: Scottish Government, Health Directorate, Health Protection Division Framework, ODT Policy team – Sharon Grant sharon.grant@gov.scot mobile 07950653513
- Committees that the frameworks are being actively shared with:
  - Health, Social Care and Sport Committee
  - Convener of the Constitution, Europe, External Affairs and Culture Committee.

2. Points for the Parliamentary committees to note

a. Procedural

- Date of JMC(EN)/portfolio Minister sign-off of the provisional framework: 4 March 2021

b. Content

- Purpose of the frameworks

Both frameworks aim to maintain a compatible minimum set of safety and quality standards between the UK Government, Scottish Government, Welsh Government and the Northern Ireland Executive to make it easier for blood components, organs and non-reproductive tissues and cells to continue to be shared across the UK. The Frameworks set out a process by which any administration can suggest future changes to the standards and how such a proposal will be collectively considered before one or more administration(s) introduces a change to the relevant Regulations. It will allow for divergence by one or more administration(s) as required, in order to respond to policy aims or objectives

No issues are particularly contentious, although the impact of the Northern Ireland Protocol (NIP) on the ability of the Northern Ireland Executive to make changes to Regulations in Northern Ireland will depend on the nature of any future proposals for legislative change (either from other UK nations or the EU). The NIP specifies that Northern Ireland must follow EU rules on the safety and quality of blood, organs, tissues and cells. As changes are made to areas in scope of those rules,

they will apply directly, or require implementation, in Northern Ireland as they do now.

Issues related to the safety and quality of blood, organs, tissues and cells will continue to be considered on a four nation basis. Northern Ireland's participation in the Frameworks will ensure decisions that are taken in England, Scotland and Wales fully consider the potential impacts across the UK before any changes are taken forward.

The text at section 2 in the Frameworks titled "The Protocol on Ireland /Northern Ireland" (starting at paragraph 4.16 in both Frameworks) has changed from the version published in March 2021 to reflect that the text relates to a factual consideration of the policy interactions between the Protocol and Frameworks, which is distinct from the wider political discussion relating to the Protocol and Article 16.

- Relevant legislation

The key pieces of legislation are:

- **Blood:** The Blood Safety and Quality Regulations 2005
- **Tissues and cells**: The Human Tissue (Quality and Safety for Human Application) Regulations 2007
- **Organs:** The Quality and Safety of Organs Intended for Transplantation Regulations 2012

The relevant EU legislation is listed in each of the Frameworks.

- Stakeholder Engagement

There is currently good information sharing and collaboration across the UK and the Framework agreements to support the continuation of stakeholder engagement. Any feedback received from stakeholders has been discussed and where appropriate incorporated into the development of the Frameworks.

Phase Three Stakeholder Engagement

Stakeholder consultation was co-ordinated by the Department of Health and Social Care on behalf of the four nations. This consultation enabled policy officials to test provisional policy proposals with sector-specific experts from across all four nations of the UK. This informed further policy development and decision-making in a robust and transparent way.

In November 2020, feedback was gathered from stakeholders as part of Phase three of the Common Framework process.

For the Blood Safety and Quality Framework, engagement was with the four UK Blood Services: including, the Medicines and Healthcare products Regulatory Agency (MHRA); the Scottish National Blood Transfusion Service (SNBTS), NHS Blood and Transplant (NHSBT); the Advisory Committee on the Safety of Blood,

Tissues and Organs (SaBTO); and the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Processional Advisory Committee (JPAC) were consulted.

For the Organs, Tissues and Cells Framework, NHSBT, SaBTO, JPAC, Scottish National Blood Transfusion Service, Human Tissue Authority (HTA), Welsh Transplantation Advisory Group, Cardiff and Vale University Health Board, Health and Social Care Northern Ireland (HSCNI) and the Welsh Renal Clinical Network were consulted.

Stakeholders agreed with the rationale and scope of the Frameworks and highlighted the impact of the NIP. Most of the detail they requested was already included within the framework documents. The only substantive change was the addition of references to the Medicines and Medical Devices legislation and Human Medicines legislation, as reagents (medical devices) are used in the collection and processing of blood, organs, tissues and cells.

Engagement has continued with stakeholders particularly JPAC, SaBTO, HTA and MHRA on the provisional Frameworks that were published in March.

Evidence Session (May 2021)

The House of Lords Common Framework Scrutiny Committee (CSFC) are responsible for scrutinising and considering matters relating to all the Common Frameworks. DHSC officials have been engaging with the Committee in preparation for UK Parliamentary scrutiny. The CSFC held an Evidence Session in May to discuss the Provisional Blood Safety and Quality Framework, the Provisional Organs, Tissues and Cells Framework and the Provisional Public Health Security framework. MHRA attended and provided a regulators perspective. The other stakeholders in attendance were the Faculty of Public Health in Scotland, who shared experience as a convener, and the Nuffield Trust, who provided a broad policy context from the think tank perspective. The session was beneficial and helped the Committee to better understand the policy context that the frameworks will function within and hear stakeholders' views on the frameworks.

Future Stakeholder Engagement

The intention is to gather further feedback from stakeholders once scrutiny across the UK is complete.