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Llywodraeth Cymru
Welsh Government

Eich cyf/Your ref
Ein cyf/Our ref: MA/EM/3486/21

Russell George MS
Chair
Health and Social Care Committee

cc Huw Irranca-Davies, Chair, Legislation,
Justice and Constitution Committee

17 January 2022

Dear Russell,

Thank you for your letter of 17 December regarding the provisional Common Frameworks for Blood Safety and Quality, and Organs, Tissues and Cells (apart from embryos and gametes). I shall answer your questions in the order in which they were asked.

General

Question 1: Why are common frameworks needed for these policy areas?
These frameworks are necessary to ensure alignment on any future legislative changes in order to preserve a robust UK-wide regime on safety standards. Ministers in each part of the UK have powers to legislate in relation to quality and standards of blood, organs, tissue and cells. However all four UK nations agree the need to maintain the UK-wide offering and allocation schemes for organs and the mutual aid arrangements which are in place across the blood services. These arrangements allow for blood, organs and tissues donated in one part of the UK to be utilised in other parts of the UK and, in the case of blood, for the different blood services to support one another in times of shortage.

Question 2: The Welsh Government has taken on new functions in these policy areas following the UK's exit from the EU. How has the Welsh Government ensured that it has the resources and expertise to exercise these functions effectively?
Blood, organ, tissue and cell safety and quality areas fall within the devolved competence of the Senedd. The UK Government has already made, with the Welsh Ministers' consent (in 2019 and amended in 2020), the following three Statutory Instruments which maintain the current quality and safety standards for blood, blood components, organs, tissues and cells, and make necessary amendments to legislation to reflect the EU becoming a 'third country':

- The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019;
- The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019; and
- The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019.

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Responsibility for these areas falls across two policy teams in the Welsh Government's Health and Social Services Group. Both teams have expertise in the areas concerned and these officials would respond to any proposals to exercise these functions both from within Wales or elsewhere in the UK.

Question 3: What role does the Welsh Government have in oversight of the work of the Independent Advisory Committee on the Safety of Blood, Tissues and Organs and the Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee?

The UK Government's Department of Health and Social Care's leads an Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO), which provides policy advice to Ministers in all four countries of the UK on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion and transplantation. The Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) provides detailed services guidelines for the UK's blood transfusion services. Officials from the Devolved Governments and/or blood services can attend these meetings as observers and will take account of any recommendations the committees make in the context of services in Wales.

Managing divergence

***Question 4: The frameworks state that they will allow for 'necessary divergence' within the UK. Could you set out what 'necessary' means in this context*?**

'Necessary divergence' in this context could be a change which is needed in order to address any specific operational requirements in a particular country; for example, there may be a need to provide additional information or testing for donors beyond that which is set out in the current regulations or schedules in order to respond to a local matter. At this stage there are no specific areas of divergence in contemplation, however it is important to retain the ability to diverge from other parts of the UK if deemed appropriate in the future, even if the circumstances of that divergence are as yet unforeseen.

Question 5: Do you consider that the frameworks give the Welsh Government and the Senedd appropriate scope to make law and policy for Wales?

Yes. I am content that for the two frameworks in question, the powers of Welsh Ministers and the Senedd are not impacted by these frameworks.

Question 6: Will the frameworks have any impact on any existing or planned Welsh legislation or policy?

Not as currently envisaged for these specific policy areas. There are no current plans to make any changes to Welsh legislation or policy in relation to the areas covered by the frameworks.

Question 7: How would the frameworks affect the Welsh Government's ability to respond to urgent situations, such as emerging new diseases?

As set out above for Question 4, these specific frameworks allow for necessary divergence to take place to enable each UK country to respond to individual factors. Therefore the frameworks in themselves do not affect this ability. However, they do require all UK countries to consider how any changes might impact on other parts of the UK, which is a welcome and necessary step.

Question 8: The European Commission intends to adopt changes to legislation on blood, tissues and cells in early 2022. Does the framework allow sufficient scope for the Welsh Government to make equivalent changes for Wales, and do you plan to do this?
We are aware of the plans to revise the EU Directives on the safety of blood, tissues and cells and we will consider, with the other governments in the UK, the implications of any changes. We would not propose to make any unilateral changes in Wales, preferring to take a joint approach with the rest of the UK in response to any changes in the EU, providing that the detail of any such joint approach is appropriate for Wales.

Question 9: As part of its review of retained EU law, the UK Government is asking UK Government departments to consider whether such law should be amended or repealed by 'an accelerated process'. Would such changes be considered through the framework processes, and (if so) how?
The frameworks exist in relation to the application of retained EU law. I would envisage a separate process to be undertaken in the event that these laws should be proposed for amendment or repeal. We will work with UK Government as its review of retained EU law is taken forward, as well as the other Devolved Governments, to understand any potential implications for Wales.

Question 10: Can the Welsh Government confirm that neither framework will interact with the UK Internal Market Act?
It has been recognised during the development of these frameworks that there is an intersect between these frameworks and the UK Internal Market Act (UKIMA). In the event that there is policy divergence and a proposal by one government to regulate in this policy area in a way in which could engage the application of the UKIMA market access principles, the "Process for considering UK Internal Market Act exclusions in Common Framework areas" will apply[1].

International obligations

Question 11: What international obligations are there in these policy areas?
In relation to these specific policy areas, NHS organisations and the regulatory authority must follow the existing quality and safety standards as set out in the Blood Safety and Quality Regulations 2005, the Quality and Safety of Organs Intended for Transplantation Regulations 2012 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 which set out various requirements, for example for the traceability, import and export of these materials internationally.

Question 12: How does the framework take international obligations into account?
These frameworks do not specifically cover international obligations – and so do not alter current obligations with which organisations are already familiar.

Question 13: How will the framework be amended in future to reflect a new international obligations?
As for Question 12.

Governance and dispute resolution

Question 14: Do you consider the dispute resolution mechanisms for the frameworks to be robust enough for their intended purpose?
Yes, I believe the mechanisms are robust and proportionate. These have been jointly developed and agreed by the four UK nations.

[1] Process for considering UK Internal Market Act exclusions in Common Framework areas

Question 15: Who will be the final arbiter in the event of a dispute, and will there be a right of appeal in the event that one of the parties is dissatisfied with the resolution of a dispute?
These matters are designed to be agreed through discussion and appropriate levels of escalation, as set out in the framework documents. Our experience of dealing with other governments in the UK in relation to legislative matters in these policy areas is that there is generally a high level of willingness to look for mutually acceptable solutions. It should also be noted that the Interministerial Standing Committee, established under the Intergovernmental Relations Review, will monitor the frameworks programme including any obstacles to progress.

Question 16: Will the Welsh Government notify the Senedd of disputes raised through the framework?
Yes, I am content to commit to writing to the appropriate committee(s) in the event that there are any disputes raised.

The development of the frameworks

Question 17: How did the Welsh Government engage with stakeholders on the development of the frameworks? How does each framework reflect the responses of stakeholders in Wales?
The UK Government's Department of Health and Social Care led a stakeholder engagement exercise for the frameworks, and we ensured that this included appropriate stakeholders in Wales, including the Welsh Blood Service (WBS), the Welsh Transplantation Advisory Group (WTAG) and transplant teams. The comments received from Welsh stakeholders were largely supportive of the content of the draft frameworks. The WBS provided more substantive comments on the text of the document and changes were made to reflect those comments, for example around interdependencies with medical devices legislation.

Review and revision

Question 18: How will the Senedd and stakeholders be updated on the continuing operation of the frameworks?
Officials will monitor the operation of the specific frameworks relevant to their policy areas and seek input from stakeholders as appropriate, for example with WBS and WTAG. In a more general sense, the Interministerial Standing Committee will monitor the progress of the frameworks programme in order to fulfil the role given to it by the Intergovernmental Relations Review, as outlined in the UK Government's progress update of March 2021, to '*Provide oversight of the common frameworks programme and its governance arrangements'*. The expectation is that reports on frameworks will be public documents once they are signed off by portfolio Ministers and will be made available to the relevant committees in the four nations as well as relevant stakeholders.

Question 19: How will the Senedd and stakeholders be able to contribute to the review and amendment process for the frameworks?
The framework documents set out that a review will take place after one year. Third parties can be used by any Party to the Framework to provide advice at any stage in the process and so we will seek views from relevant stakeholders during the review process as appropriate.

Question 20: If changes are made in future, how will the Senedd be notified? What scrutiny procedure will apply to the changes?
If changes are made to the frameworks then these will be notified to Senedd committees in order for them to carry out the level of scrutiny they deem appropriate and necessary.

Yours sincerely,

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