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Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol  
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Llywodraeth Cymru  
Welsh Government

Ein cyf/Our ref LF/LG/0137/13

David Melding AM  
Chair  
Constitutional and Legislative Affairs Committee  
National Assembly for Wales

4

March 2013

*Dear David,*

**Human Transplantation (Wales) Bill (“the Bill”) – additional information**

Thank you for your letter of 13 February following my attendance to give evidence to your Committee on 4 February. You have asked for clarification on a number of points, which I will deal with in turn.

**1. The type of person likely to be exempted from being an appointed representative by regulations under section 7 of the Bill**

Section 7 of the Bill includes a power for the Welsh Ministers to prescribe in regulations who may not act as an appointed representative. The power is equivalent to one set out in section 4 of the Human Tissue Act 2004 (the 2004 Act) and vested in the Secretary of State. The regulation-making power under the 2004 Act has never been used.

However, it is important for a person to have confidence in the person they appoint to make decisions about organ donation and Welsh Ministers may wish to prescribe who may not act in this capacity in regulations in order to give the requisite level of protection to individuals. People appointing a representative should have confidence the person they choose is someone who is capable of understanding the issues around organ donation and who will then be able to go on and make a decision on their behalf. As I indicated in Committee, the main category of person exempted therefore is likely to be those who lack capacity, since it is unlikely such a person would be able to understand the issues involved in organ donation and come to a decision on behalf of the deceased. There might well be other suitability considerations and we are liaising with the Human Tissue Authority on any potential areas we may wish to set out in regulations.

## **2. Further details on section 8 (activities involving materials for living adults who lack capacity to consent) and in particular the likely timing of the regulations to be introduced by this section**

Section 8 of the Bill deals with living donation from adults who lack capacity to give consent. The use of the term “deemed” in this context is different to its use at section 4 of the Bill, which provides for a soft opt-out system of consent to deceased organ donation.

This section includes a power for the Welsh Ministers to prescribe in regulations when deemed consent can apply in relation to the storage and use of relevant material. Section 8(2) sets out a best interests test on the face of the Bill which means consent to an activity may be deemed if it is done in the person’s best interests or is done in circumstances of a kind specified in regulations.

I have considered this further following discussions at Committee and I have decided to bring forward a Government amendment to clarify this provision. The change I propose to make will be to amend section 8(2) to retain the power for Welsh Ministers to set out in regulations the circumstances for deeming the consent of a living adult who lacks capacity but to remove the “best interests” test currently at section 8(2)(a). This brings the provision closer to section 6 of the 2004 Act. My intention would then be to set out the best interests test in regulations rather than on the face of the Bill, as has been done by the Secretary of State in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. The regulations would be subject to the affirmative procedure. This would remove any queries which have arisen in relation to section 8(2) about whether this leaves potential for Welsh Ministers to prescribe circumstances other than those which are in a person’s best interests for their consent to be deemed.

## **3. Clarification on the procedure to be used for issuing codes of practice under section 14 of the Bill.**

Section 14(4) of the Bill amends the 2004 Act and provides that the Human Tissue Authority will send a draft of any code relating to transplantation activities carried on in Wales to Welsh Ministers for approval. In turn, Ministers must lay such a code before the Assembly for 40 days. Currently as drafted the Bill requires the use of the negative procedure. Having listened to the points made by the Committee I am persuaded this should be amended to allow for the affirmative procedure.

There are other codes of practice issued by the Human Tissue Authority which are not concerned with matters in the Bill relating to transplantation in Wales (e.g. research; public display, etc). These codes are laid before Parliament and not the Assembly however there is a requirement to consult Welsh Ministers first. We have taken the opportunity in the Bill of making a minor amendment to the 2004 Act to change references to the “National Assembly for Wales” to “Welsh Ministers”. This more accurately reflects the constitutional position as well as the practical reality of approval of these more general codes by the Welsh Ministers.

I hope these explanations will be helpful to the Committee.

Regards  
Lesley

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