

Consultation Response

Consultation on the draft content of the Human Tissue (Authorisation) (Excepted Body Parts) (Scotland) Regulations

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Introduction

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Our Criminal Law Committee welcomes the opportunity to consider and respond to the Scottish Government consultation on the draft content of the Human Tissue (Authorisation) (Excepted Body Parts) (Scotland) Regulations (the consultation). The committee has the following comments to put forward for consideration.

The interests of the consultation span the role of Crown Office and Procurator Fiscal Service (COPFS) where members of the committee are current or former members.

General

The Human Tissue (Authorisation) (Scotland) Act 2019 ('the 2019 Act') provides for a deemed authorisation system of deceased organ and tissue donation for transplantation in Scotland with an 'opt-out' system to replace the current 'opt-in' model. Deemed authorisation will only apply to the commonly transplanted organs and tissue and will not apply to novel or rare transplants. The consultation signals the intention to lay draft Regulations before the Scottish Parliament¹ to provide the definition of what would comprise an "excepted body part" in terms of section 7(5) of the 2019 Act amending the Human Tissue (Scotland) Act 2006.

The consultation recognises that medical science is advancing and the need for clarity for the public on what is included/excluded given the stressful and emotive time and in what circumstances that these will apply.

We note the reference to "there being a small number of novel transplants from deceased donors being developed in the UK [and] several transplant procedures currently undertaken in other countries, which may be taken forward in the UK at some point in the future, for example penis

¹ Section 7(6) of the 2019 Act that are subject to the affirmative parliamentary processes.



transplantation." Ensuring that the public are aware that future changes to the list of excepted body parts would require further scrutiny by the Scottish Parliament and further regulations is important. Guidance from the medical experts and as the consultation recognises "the need for careful evaluation at each stage of its development to ensure that it is safe, effective, ethical for patients, and meets the needs of the population" will be required in seeking any further amendments which presumably could be planned and incorporated at the relevant time.

We are responding only to Question 4 of the consultation:

Question 4: Do you have any other comments on this consultation?

There are a number of safeguards within the 2019 Act to ensure that a transplantation donation does not proceed where it would be against the wishes of the potential donor.²

We have three observations to make:

1. COPFS

There is a need to be aware of the Organ and Tissue Donation: COPFS and SDTG agreement (updated December 2017)³ (the Agreement).

Paragraph 1.12 of that Agreement tends to imply that any change in legislation (as outlined in the consultation) that was anticipated "is not expected to affect the matters covered in this Agreement - in other words it will not impact on the need for the Procurator Fiscal (PF) to consent to organ and/or tissue donation proceeding in cases where a patient's death needs to be reported to the PF."

It should be confirmed that the Agreement still applies where the interests of the criminal law or COPFS investigation are paramount and considered first once the regulations are laid.

There is also a need for up to date information regarding the position on organ transfer to be available on the COPFS and relevant websites as there can be no question of any organ transfer until COPFS have in effect discharged the body and/or require the retention for any of their purposes (FAI etc) of any organ samples.

2. Education, training and awareness raising

Once the regulations come into effect, we question what the Scottish Government's plans are to raise awareness for the public on any implications arising from the 'opt out' policy.

² Paragraph 12 of the consultation

³ https://www.gov.scot/publications/agreement-between-crown-office-procurator-fiscal-service-scottish-donation-transplant/



How does the Scottish Parliament intend to monitor the success or otherwise of the change to the 'opt out' system? Is there any provision for reporting to the Scottish Parliament?

3. Cross border implications

In terms of paragraph 25 of the consultation, we note that organ and eye donation and transplantation are coordinated across the UK by NHS Blood and Transplant (NHSBT). An organ donated in Scotland can be transplanted into a recipient in another part of the UK and similarly for organs donated in other parts of the UK to people in Scotland.

This is important. Organs can be very specific; so, the ability to transfer cross border is very important. Aligning the practices of the respective countries is essential. That ties with the point under paragraph 27 of the consultation suggests that "Similar regulations to those proposed in Scotland are in effect in Wales and have been consulted upon in England,⁴ and they reflect the respective legislation in those jurisdictions. Once the regulations are laid, have all counties similar regulations in place as there should not be any discrepancy on either what organs may be used or any delay in transplanting such organs as required irrespective of where the patient is located. What seems important is the consistency of practice across the countries. Could this be clarified how alignment will or is intended to work.

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/798467/Organs_an d_tissues_to_be_excluded_from_the_new_system_of_organ_and_tissue_donation_in_England_-_consultation_document.pdf



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