EXECUTIVE NOTE

The Human Tissue (Removal of Body Parts by an Authorised Person) (Scotland) Regulations 2006 SSI/2006/327

The above instrument is being made in exercise of the powers conferred by sections 11(1)(b) and (2) of the Human Tissue (Scotland) Act 2006 ("the 2006 Act"). The instrument is subject to the negative resolution procedure.

Policy Objectives

The Human Tissue Act 1961, as amended by the Corneal Tissue Act 1986, which will be repealed for Scotland by virtue of section 61 of, and the schedule to, the 2006 Act, makes provision at section 1(4A) for someone other than a Registered Medical Practitioner (RMP) to remove an eye or part of an eye from a deceased person for therapeutic purposes or for the purposes of medical research or education.

The policy intention is to extend this approach to allow someone other than an RMP to retrieve certain body parts from a deceased person for the purposes of transplantation, research, education or training or audit. This will, in particular, help to offset the current shortfalls in all types of tissue for transplantation. The reference to 'body parts' reflects the wording of Part 1 of the 2006 Act, but there is no intention in practice to allow someone other than an RMP to retrieve solid organs, either in whole or in part, for transplantation because of the much greater technical difficulty involved, and the intention is to make this clear in guidance.

The policy proposal was included in the formal consultation which the Executive undertook in 2004 on the new transplantation legislation, and elicited strong support.

In practical terms, the Director of Tissue Services at the Scottish National Blood Transfusion Service (SNBTS) intends to train a small number of staff so that they can retrieve certain types of body parts, in particular tendons and bone.

The instrument provides that an RMP may authorise any person who is not an RMP to carry out the removal of a body part of a deceased person for the purposes referred to in section 3(1) of the 2006 Act.

Consultation

There has been no formal consultation on the terms of these Regulations, but key clinicians and organisations in the UK were given the opportunity of commenting on the instrument in draft, and their comments have been reflected in its wording.

Financial Effects

The instrument itself has no financial effects on the Scottish Executive or any other organisation.

Regulatory Impact Assessment

The draft Regulations have no impact on businesses, charities or voluntary bodies. The effectiveness of the new arrangements will be overseen by SNBTS and the UK Transplant (UKT) Division of NHS Blood and Transplant. In the light of this, a formal Regulatory Impact Assessment was considered unnecessary. Tissue retrieved, whether by an RMP or someone authorised by an RMP, for human use comes within the system of licensing which has been put in place for the UK by the Human Tissue Authority (HTA) to secure compliance with the EU Directive on the Safety of Tissue and Cells. By agreement with the Scottish Ministers, the HTA is acting as the Competent Authority for Scotland in terms of the Directive, and the therapeutic tissue banks in Scotland are subject to the licensing arrangements which the HTA has been developing.

Health Department: Healthcare Planning Division
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