

EXECUTIVE NOTE

The Human Tissue (Scotland) Act 2006 (Human Organ Transplants Act 1989 Transitional and Saving Provisions) Order 2006 SSI/2006/420

The above instrument is being made in exercise of the powers conferred by section 58 of the Human Tissue (Scotland) Act 2006 (“the 2006 Act”). The instrument is subject to the negative resolution procedure.

Policy Objective

The Human Organ Transplants Act 1989, which applies across the UK, prohibits the donation of organs involving a living donor and recipient who are genetically unrelated to one another, unless a reference has been made to ULTRA (the Unrelated Live Transplants Regulatory Authority) and ULTRA is satisfied as to certain matters in terms of the Human Organ Transplants (Unrelated Persons) Regulations 1989.

Cases involving living donation where the potential donor and recipient are genetically related are not subject to scrutiny by ULTRA but are subject to arrangements for testing the genetic relationship, as set out in the Human Organ Transplants (Establishment of Relationship) Regulations 1998.

The 2006 Act provides for repeal of the 1989 Act for Scotland with effect from 1 September 2006. It introduces new arrangements, which involve scrutiny of all cases of living donation, whether the parties are unrelated or related, by the Human Tissue Authority on behalf of the Scottish Ministers. The 2006 Act contains no provisions of a transitional or saving nature in relation to living organ donation. As a result, any cases of unrelated or related donation begun under the existing arrangements but not completed by midnight on 31 August 2006 would involve the committing of an offence, since HTA approval had not been obtained in accordance with section 17 of the 2006 Act and the provisions of the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006.

It would be possible to avoid the problem by arranging that the approval of the HTA should be sought in any such cases. That carries a risk, however, that a process which was already well advanced would be delayed or halted, possibly with damaging consequences to both the potential donor and the potential recipient. The basis of the new application would not relate to any benefit to the couple concerned, but would be intended purely to avoid the commission of an offence stemming from the introduction of the new system of scrutiny.

The Order therefore provides that transplant procedures involving organ donation between living relatives should be allowed to proceed after 1 September without HTA approval, provided that the fact of the genetic relationship had been established under the arrangements for testing the genetic relationship, as set out in the Human Organ Transplants (Establishment of Relationship) Regulations 1998. This transitional arrangement would remain in place for 6 months, so any procedure which benefits from the transitional arrangements would need to take place by 28 February 2007.

For cases in which the donor and recipient are unrelated, the Order provides that where a registered medical practitioner has referred a case to ULTRA in accordance with regulation 3 of the Human Organ Transplants (Unrelated Persons) Regulations 1989, and ULTRA has

received that reference before 1 September 2006, the relevant provisions governing the present arrangements for the scrutiny of unrelated live transplants shall continue to apply, and the relevant provisions of section 17 of the 2006 Act shall not apply when they come into effect on 1 September 2006. The Department of Health is making arrangements for the chair and members of ULTRA to remain in office until 31 March 2007 to allow for completion of all cases referred to them up to 31 August 2006.

Consultation

The terms of the Order have been the subject of informal consultation with those involved in programmes of living donation in Scotland. There has also been consultation with the Department of Health to ensure that the terms of the Order are consistent with the equivalent instruments being made under the Human Tissue Act 2004, which applies to the rest of the UK.

Financial Effects

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

Regulatory Impact Assessment

The Order has no impact on businesses, charities or voluntary bodies. Since it provides for the continuation of existing arrangements, and the number of cases which will benefit from the terms of the Order is extremely small, the Order will have no regulatory impact overall.

Health Department: Healthcare Planning Division
August 2006