

EXECUTIVE NOTE

The Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 S.S.I. 2006/390

The above instrument is being made in exercise of the powers conferred by sections 17(3), (4), (5) and (7), 18(2) and 59(1)(b) of the Human Tissue (Scotland) Act 2006 (“the 2006 Act”). The Instrument was subject to affirmative resolution procedure.

Policy Objectives

The Scottish Executive supports positive attitudes towards the donation of organs and tissue for transplantation. The organs and tissue which become available from cadaveric donors fall far short of Scotland’s requirements, and for many years there has been an increasing emphasis on the role which donation of organs and tissue by the living can play in reducing that shortfall. Advances in medical and surgical techniques have gradually extended the possibilities of living donation. Kidney donation remains the most common form, but it is also possible to donate part of the liver and lungs. Donation by the living of a variety of tissue, especially skin and bone, is also possible.

The Executive carried out a consultation during 2004 on new legislation on the donation and transplantation of organs and tissue from both the living and the dead. The responses to the questions dealing with living donation, which is governed at present by the Human Organ Transplants Act 1989, showed strong support for the introduction of new forms of donation and these are reflected in the Regulations. They also take account of the position in England, and broadly parallel Regulations which are being made under section 33 of the Human Tissue Act 2004 (“the 2004 Act”). Across the UK, scrutiny of living donation will extend the present arrangements, which apply only where the potential donor and recipient are unrelated, to all cases of living donation. This approach was also supported in consultation responses. The degree of scrutiny will vary according to the circumstances of the donation.

The 2006 Act repeals for Scotland both the 1989 Act and ULTRA (the Unrelated Live Transplants Regulatory Authority) which was set up by Regulations under the 1989 Act. The 1989 Act Regulations are being replaced by these Regulations to regulate live transplants. Section 17 of the 2006 Act makes it an offence to remove an organ, part of an organ or tissue from the body of a living person and use it for transplantation, but provides that Regulations can be made to disapply the restriction on transplantations involving a living donor provided certain conditions are satisfied. The main requirements are that the donor should have authorised the removal and use of the organ or tissue for transplantation, has not been subject to coercion and has not received any reward. In relation to children and adults with incapacity, the offences relating to organ removal and use may only be disapplied in the context of a domino organ transplant operation, whilst the offences relating to removal and use of tissue may only be disapplied where that tissue is regenerative tissue.

To achieve as much consistency as possible, the Scottish Ministers have agreed with the Human Tissue Authority, which has been set up under the 2004 Act, that it will deal with Scottish cases on their behalf. Section 54 of the 2006 Act enables the Scottish Ministers to make arrangements for assistance with certain of their functions, including those under sections 17(3), (4) or (5) and 18 and it is intended that the HTA will assist the Scottish Ministers under this statutory arrangement. The arrangement will be reflected in a Service

Level Agreement with the HTA, and in the Codes of Practice and guidance for clinicians which the Authority is developing. Acting for the Scottish Ministers, the Authority will require to be satisfied that the provisions of the 2006 Act and the Regulations have been met before agreeing that living donation can proceed.

A further consultation during the passage of the Human Tissue (Scotland) Bill through the Parliament dealt specifically with donation by Adults with Incapacity (AWI). Where living AWI were concerned, the responses were almost unanimous that the only forms of donation which should be open to them were donation of an organ as part of a domino organ transplant operation and of regenerative tissue, such as bone marrow. The Regulations seek to apply the principles and protections of the Adults with Incapacity (Scotland) Act 2000 to these forms of donation by a living AWI. The Regulations also incorporate a very similar approach to donation by living children, and again this policy was approved by the Parliament in its consideration of what is now the 2006 Act.

Financial Effects

The instrument itself has no financial effects.

Regulatory Impact Assessment

The draft Regulations have no impact on businesses, charities or voluntary bodies. Living donation has been subject to statutory regulation since 1989, so the present Regulations do not involve the introduction of a new type of regulation. The Human Tissue Authority is establishing itself as a proportionate regulator, and inviting it to discharge this function for Scotland avoids the need for the creation of a regulatory body specifically for Scottish cases of living donation. There is strong support across all sectors for the regulation of this activity, as it protects the interests and safety of potential donors and recipients of organs and tissue. In the light of these considerations, a formal Regulatory Impact Assessment was considered unnecessary.

Health Department: Healthcare Planning Division
May 2006