



Human Tissue Authority

Strategic Plan 2008/09 – 2013/14

Introduction

From Shirley Harrison, Chair of the Human Tissue Authority

The Human Tissue Authority (HTA) published its first three year Strategic Plan in 2005. Unsurprisingly for the first two years following the HTA's establishment, the emphasis has been on creating the new organisation and developing a new regulatory framework. To some extent, that plan was shaped by the Government's proposal to create the Regulatory Authority for Tissue and Embryos (RATE) by bringing together the HTA and the Human Fertilisation and Embryology Authority (HFEA).

Much has changed in the past year. The HTA is now firmly established and is implementing the regulatory frameworks for each of the sectors that fall within its statutory remit. We have continued to apply the principles of better regulation and have shown too that good regulation need not be risk averse and can have a positive effect on standards. None of this would have been possible without the initiative and energy of our staff who have brought a huge breadth of knowledge and expertise to the organisation.

The landscape has changed too. The Joint Parliamentary Scrutiny Committee recommended in August this year, and the Government accepted, that the creation of RATE should not go ahead. This means that the HTA will continue as a separate body.

The HTA has now established itself as a regulatory body that is perhaps unique in terms of its wide remit under the Human Tissue Act 2004 (HT Act); and it is acknowledged as being at the forefront of regulation under

the European Tissue and Cells Directive (EUTCD). Against this backdrop and the Government's decision that the HTA should remain as a stand-alone body, we believe that now is the right time to take a fresh look at our strategic objectives.

Independent evaluation has shown that we have rapidly established a positive relationship with our public and professional stakeholders. We want to maintain that relationship.

We are strongly wedded to our principles of better regulation and value for money for the taxpayer and our licence fee payers. We are mindful that we should not exceed our statutory remit, but we are also aware of the responsibility that the government places on us to keep the regulatory burden light.

Our revised strategic objectives rightly bring these important roles to the fore.

Our remit and structure

The HTA was established on 1 April 2005 under the HT Act, which extends to England, Wales and Northern Ireland. The HTA is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health.

The Authority's Chair and members were appointed by the Secretary of State for Health. The Chair and half of the members are lay, with the remainder being professionals drawn from some of the groups who are affected by implementation of the HT Act.

The Authority is supported by an Executive of 42 staff.

The HTA has two principal statutory functions. The first is to inform the public and the Secretary of State for Health about issues within our remit. We fulfil this remit by issuing Codes of Practice including:

- Consent
- Donation of organs for transplantation
- Post mortem examination
- Anatomical examination
- Removal, storage and disposal of human organs and tissue
- Donation of allogenic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation
- Public display
- Import and export of human bodies, body parts and tissue.

We are also responsible for ethical approval of all transplants of solid organs from living people, and of bone marrow from incapacitated adults and children.

The second of our principal statutory remits is to license and inspect the following sectors:

- anatomy
- post mortem services
- tissue for human application (see below)
- research
- public display

The HTA is also one of two Competent Authorities under the EUTCD for regulating establishments importing, procuring, testing, storing, and processing and distributing tissue for human application.

Our strategic aim and objectives

The HTA's strategic aim is to create a regulatory system for the removal, storage, use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence. In support of this aim, the strategic objectives for the period of this plan are to:

Implement Human Tissue legislation in a way that promotes safe and ethical practice and is conducted in accordance with the wishes of the individual.

Our statutory remit remains our priority. We will continue to implement and interpret the principles embodied in the HT Act, EUTCD, and any future relevant European legislation. Our main aims are to:

- ensure that the wishes of the individual are respected
- raise and maintain standards to ensure that tissue and cells are safe to use in transplants and provide the best possible basis for research
- operate our regulatory framework in a way that gives confidence to professionals and the public.

Play a leading role in the development of the regulation of human tissue.

The HTA has accumulated a wealth of practical expertise in implementing the HT Act and the EUTCD. We are keen to use this experience to play a leading role in helping stakeholders understand and implement these pieces of legislation, to initiate debate and share lessons learnt.

We will also continue to work with the other Competent Authorities in the European Community and DH to develop a coherent, accurate, collective understanding of how to implement the EUTCD.

Our experience as the regulator of all organ donations from living people puts the HTA in a unique position to contribute to the development of policy in this area.

The Government has set a course to lighten the regulatory burden across industry and the public sector. We will continue to work with other organisations to avoid duplication and over-interpretation of legislation so as to minimise regulatory impacts. We will also develop horizon-scanning functions so we are ready to fulfil Ministers' wishes.

Maintain the confidence of the public and professionals and continue to work in partnership with them.

A characteristic of the HTA has been our desire to engage, communicate and work with all our stakeholders – not just through formal consultations, but equally importantly to develop our regulatory standards, policies and guidance. We recognise that a two-way dialogue is vital if the regulatory framework we implement is, and is seen to be, practicable, proportionate and fit for purpose.

We will continue to involve stakeholders to help us refine our guidance, standards and regulatory methods. We will build on the successful results from the evaluations we carried out in 2007, increase our level of

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Our strategic aim and objectives

engagement, and further improve and refine our communications routes and materials. In order to ensure our remit is effectively implemented, we also will continually review our contacts to engage new audiences.

Become an organisation that makes the best use of its knowledge and the information it holds.

Accuracy, consistency and timeliness of guidance and responses to enquiries is essential if we are to meet our remit in the proper fashion and if we are to maintain the confidence of our stakeholders. We will continue to build and refine over the coming years the Knowledge Management programme which we started in 2007. We will also continue to gather information from our regulatory activities and stakeholder engagement and feed them back to each of the regulated sectors to help drive up standards.

Develop staff to make the HTA a distinctive, dynamic organisation that people want to work for.

We want to demonstrate the HTA's continuing commitment to staff by delivering an education and training programme that helps us achieve our demanding goals and supports their wider development. We want especially to empower them to make decisions and to encourage them to use their creativity to deliver our statutory remit to a high standard. We will support them by providing them with the time and space they need to achieve these goals.

Continue to apply the principles of better regulation and provide value for money for the taxpayer and licence fee payer.

We will continue to apply the principles of better regulation in a way that is pragmatic, workable, and provides best value for money. We will manage our finance and governance systems in order to find the most economical, efficient and effective ways of delivering the service.

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