



# Human Tissue Authority

## Strategic Plan 2010/11 – 2012/13

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## Introduction

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### From Diana Warwick, Chair of the Human Tissue Authority

I am delighted to introduce the Human Tissue Authority's strategic plan for the next three years – my first since taking up position as Chair on 1 January.

Our achievements since we began regulating in 2006 are remarkable. The HTA's 67 staff license 850 premises and approve more than 1000 organ transplants from living donors a year. The Hampton Implementation Review published in July 2009, independently assessed the HTA and praised us on our adherence to all five principles of Better Regulation. In particular, we were rated highly on minimising inspection and data-collection burdens, and the quality and availability of our advice and guidance. This reflects the feedback we receive from our stakeholders, not only from the formal evaluations we conduct, but also as we go about our day-to-day business.

The HTA has established itself as a modern, high-performing and forward-looking regulator. We have been progressive in safeguarding the storage and use of human tissue – work that is vitally important to reassure the public that their wishes are respected and that tissue is used appropriately.

There are many challenges facing us, however, including the uncertain financial climate, medical and scientific advances, and heightened awareness of patient safety issues. *The Smarter Government* agenda, for example, throws into sharp relief the importance of our efforts to continually seek more efficient and more effective delivery of services. Many of those we regulate are affected by these challenges too, including the NHS, academia, local councils, and the private sector.

We will, over the next three years continue to work closely with our stakeholders and ensure our decisions are based on the best available evidence. We will achieve this by making the best possible use of our highly skilled staff and other resources, and avoiding unnecessary burdens on licence fee payers and the public purse.

We will continue to adopt an approach that supports scientific and medical advances by providing a regulatory framework that is permissive and gives confidence to professionals and the public. We will also continue to meet our statutory remit in a way that supports the use of human tissue for important purposes such as teaching and patient safety. At the same time, I want the public to remain confident that tissue will not be taken or used without their consent.

Over the next three years, the Authority will operate in a way that is both consistent and flexible, against a fast-changing scientific, political, economic and legislative backdrop. These challenges can also be seen as opportunities for us to find ever more effective ways of working. I look forward to leading the HTA's Board and Executive through the coming years and ensuring we continue our dynamic and engaging approach.

## What we do – our remit

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The HTA was established under the Human Tissue Act 2004 (HT Act) to regulate activities concerning the removal, storage, use and disposal of human tissue. Our role is to support public confidence by ensuring that their wishes will be respected and that bodies and tissue are treated ethically and safely. The HTA is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health.

We have several statutory functions. One is to inform the public, professionals and the Secretary of State for Health about issues within our remit. We meet this requirement for professionals by providing guidance, including codes of practice, to support good practice; and for the public by providing information to help them make informed decisions.

Another statutory function is to regulate, through licensing organisations that store and use tissue for purposes such as research, patient treatment, post-mortem examination, teaching, and public exhibitions. We currently license more than 850 organisations and publish standards that licensed establishments must meet: on consent; governance and quality systems; premises; facilities and equipment; and disposal. We also inspect organisations to check that they maintain good standards and follow appropriate procedures. Organisations we consider to be highest risk are among the first to be inspected.

As well as licensing under the HT Act, which covers England, Wales and Northern Ireland, the HTA is the Competent Authority in the UK responsible for ensuring the safety of human tissue and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive (EUTCD). The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Q&S Regulations) brought the EUTCD into force in the UK, including Scotland.

A third statutory function is the regulation, through an independent assessment process, of the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others. The HTA also regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

## What we do – our remit

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The HTA also oversees the consent requirements of the HT Act for deceased organ donation.

The Authority (the HTA's non-executive board) comprises a Chair and Members who are appointed by the Secretary of State for Health. Its primary role is to ensure that the HTA's statutory responsibilities are met. It achieves this by setting the HTA's strategic direction and providing both support and challenge to an executive of who are responsible for the discharge of these responsibilities on a day-to-day basis.

## How we do it – our strategic aims and high level business objectives

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Our overall strategic goal 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.

The focus of our strategic plan for the next three years is to build on what we have learned in the years since the HT Act came into force and improve on what we already do well in order to deliver excellence in the regulation of human tissue. We will achieve this if we fulfil five strategic aims:

### 1. **Continuously improve the quality of our regulatory activity and our advice and guidance**

Regulatory activity and advice and guidance are our two most powerful tools in implementing Human Tissue legislation in a way that promotes safe and ethical practice and which is conducted in accordance with the wishes of the individual. Achieving an effective balance between the two makes best use of our resources to raise standards in the regulated sectors.

Continuous improvement will ensure we better maintain the principles of good regulation, becoming more transparent, accountable, proportionate, consistent and targeted

The associated objectives for 2010/11 are:

- a. To fulfil the HTA's statutory remit in relation to all licensable activity
- b. To fulfil the HTA's statutory remit in relation to advice and guidance
- c. To ensure the HTA meets the duties of the Competent Authority for Tissue and Cells
- d. To fulfil the HTA's statutory remit in relation to consent and organ donation.

## How we do it – our strategic aims and high level business objectives

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### 2. Build and develop effective relationships with stakeholders and the public, based on trust

By ensuring that the regulated sectors know how and why we have taken decisions and have had appropriate opportunities to contribute to our thinking, we will be better placed to work in partnership with them to achieve positive outcomes.

Making the wider public aware of what we do and giving them the appropriate opportunities to contribute to our thinking will improve trust in the regulatory system and in the organisations being regulated.

The associated objectives for 2010/11 are:

- a. To capture and evaluate stakeholder opinion
- b. To increase public awareness of the HTA
- c. To manage the reputation of the HTA effectively.

### 3. Be informed, influential and active in the environment in which we operate

If we are well informed about our operational environment then we are better able to anticipate new challenges and develop effective policies and responses to emerging issues. Being proactive will allow us to develop mutually beneficial relationships with outside organisations; learn from the experience of others and be a role model for other regulators.

Over the last five years the HTA has gained valuable experience which we will use to influence policy matters that are important to us.

## How we do it – our strategic aims and high level business objectives

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The associated objectives for 2010/11 are:

- a. To develop more effective horizon-scanning and knowledge management arrangements
  - b. To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with the five licensable sectors
  - c. To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with consent and organ donation
  - d. To contribute to the development and review of relevant legislation.
- 4. Have motivated and dedicated staff with the right tools in the right jobs**

Skilled and committed people are at the heart of our ability to undertake excellent regulation, build strong relationships and innovate to improve the way we manage and deliver our business.

The associated objectives for 2010/11 are:

- a. To recruit, lead and motivate staff to deliver high quality work
- b. To deliver a high quality learning and development programme
- c. To develop an environment and culture which encourage continuous improvement and uphold the organisation's values.

## How we do it – our strategic aims and high level business objectives

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### 5. Continuously improve the way the HTA is governed and managed

Good, transparent governance will improve stakeholder trust in our direction and the decisions we make. While effective management will ensure that our resources are used effectively, and deliver excellent regulation which provides value for money.

The associated objectives for 2010/11 are:

- a. To further develop governance arrangements
- b. To continuously review systems, processes and procedures to find ways of working more economically, efficiently and effectively
- c. To ensure the continued financial viability of the HTA.

## How we monitor performance

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### Budget 2010/11

The Authority relies on an executive staff to deliver the strategic plan on a day-to-day basis. To achieve this, the Authority agrees a high level budget for the coming year and the executive develops detailed business plans which set out how it intends to deliver our objectives within this budget. The high level budget for 2010/11 is shown below.

<b>Income</b>	<b>£000</b>
Department of Health funding	1,093
Licence fees	5,234
Other income	108
<b>Total Income</b>	<b>6,435</b>
<b>Expenditure</b>	<b>£000</b>
Operating costs, <i>of which</i>	
<i>Staff costs</i>	3,840
<i>Other operating costs</i>	2,006
Total operating costs	5,846
Capital charges	589
<b>Total Revenue Expenditure</b>	<b>6,435</b>

To provide greater transparency in its use of resources, the Authority has estimated the costs of delivering the strategic plan. Where direct costs are associated with specific pieces of work, these have been allocated to strategic aims. The budget by strategic aim is shown in the table below. Over the coming year we will explore the benefits of apportioning those costs which are currently unallocated.

<b>£000</b>	<b>Staff costs</b>	<b>Other costs</b>	<b>Total costs</b>
Allocated to strategic aim			
Strategic aim 1	1,787	156	1,943
Strategic aim 2	466	120	586
Strategic aim 3	231	-	231
Strategic aim 4	352	63	414
Strategic aim 5	430	20	450
<b>Total allocated</b>	<b>3,265</b>	<b>359</b>	<b>3,624</b>
Unallocated, <i>of which</i>			
Staff	575	-	575
Accommodation	-	521	521
Training and recruitment	-	353	353
IT and telecommunications	-	280	280
Other unallocated costs	-	493	493
Capital charges	-	589	589
<b>Total unallocated</b>	<b>575</b>	<b>1,647</b>	<b>2,812</b>
<b>Total expenditure</b>	<b>3,840</b>	<b>2,595</b>	<b>6,435</b>

### **Performance review**

While the executive implements and monitors delivery of the business plans, there are a number of mechanisms in place by which the Authority steers and reviews performance.

Authority meetings, which are held every two months, are the main means by which we set the direction on issues of strategic importance that emerge over the course of the year. They also provide the opportunity to assess the performance of the HTA. This is achieved through review of management information and more detailed reports on progress against elements of the strategic plan.

Each month, whether the Authority meets or not, it receives two key documents: the strategic performance review and the financial report.

### ***Strategic performance review***

This report provides a progress report against a set of key performance indicators (KPIs) which collectively give an indication of the health of the business. The Authority monitors progress using a traffic light system, whereby each indicator is assessed as red, amber or green. We receive more detailed briefing on remedial action being taken on objectives where the traffic light is showing either red or amber. The strategic performance review framework, including KPIs for 2010/11, is shown on pages 15 and 16.

### ***Financial report***

This report provides the Authority with assurances on the management of financial resources. The report provides commentary on the overall financial position, income and expenditure variances, forecast outturns and financial risks.

Both of these documents are published on the HTA website.

### **Managing risk**

The HTA has in place arrangements for the identification, management and monitoring of risk. Day-to-day responsibility for the management of strategic and operational risk is delegated to the executive but is monitored by the Authority's Audit Committee.

### **Efficiency plans**

This strategic plan includes an objective to continuously review systems, processes and procedures to find ways of working more economically, efficiently and effectively. To ensure this is realised, the Authority has in place efficiency plans which set out in more detail the action being taken. The plan includes details of how the HTA is delivering efficiencies in its regulation, use of business technology and other back office functions, how it will manage a reduction in grant in aid funding and how it is contributing towards the Government's Operational Efficiency Programme.

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**Strategic Performance Review Framework 2010/11**

Unique ref	Strategic Aim Ref	Owner	Business Plan Objective	KPI type	KPI	Delivery Update												Comments	
1. Continuously improve the quality of our regulatory activity and our advice and guidance						M	J	J	A	S	O	N	D	J	F	M	A		
<b>(a) To fulfil the HTA's statutory remit in relation to all licensable activity</b> <b>(b) To fulfil the HTA's statutory remit in relation to advice and guidance</b> <b>(c) To ensure the HTA meets the duties of the Competent Authority for Tissue and Cells</b> <b>(d) To fulfil the HTA's statutory remit in relation to consent and organ donation</b>																			
1.1	a/b	Regs	To continuously improve regulatory compliance through proportionate, consistent, transparent and risk based regulatory activity.	Measures	Number of licensing decisions (measured quarterly).														
					Number of representations and appeals (measured quarterly).														
					Proportion of representations and appeals upheld (measured quarterly).														
1.2	a/b	Regs	To continuously improve regulatory compliance through proportionate, consistent, transparent and risk based regulatory activity.	Measure/ Milestone	Proportion of all additional licensing conditions in breach over the course of the business year (measured monthly). Target to halve proportion over the business year.														
					PM Sector														
					HA Sector														
					Other sectors														
1.3	a/b	Regs	To undertake a risk based and targeted site visit inspection programme: to include all remaining post mortem sector establishments.	Measure	95% of planned PM sector establishment inspections completed by Q4 (actual proportion measured monthly).														
					Expected cumulative profile.	8	13	14	15	24	35	44	54	56	64	74	74		
					Outturn profile														
1.4	a/b	Regs	To fulfil the HTA's statutory remit to inspect human application establishments.	Measure	95% of planned HA sector establishment inspections completed by Q4 (actual proportion measured monthly).														
					Expected cumulative profile.	3	13	29	42	46	48	53	58	62	68	71	75		
					Outturn profile														
1.5	d	Pol	To manage living organ donation approvals to agreed quality standards.	Measures	Proportion of panel cases turned around within 10 working days (measured monthly). Target rate 97%.														
					Proportion of non-panel cases turned around within 5 working days (measured monthly). Target rate 97%.														

**Strategic Performance Review Framework 2010/11**

Unique ref	Strategic Aim Ref	Owner	Business Plan Objective	KPI type	KPI	Delivery Update																					
<b>2. Build and develop effective relationships with stakeholders and the public, based on trust</b> (a) To capture and evaluate stakeholder opinion (b) To increase the public awareness of the HTA (c) To manage the reputation of the HTA effectively																											
2.1	a	Comms	To evaluate public and professional opinions about the HTA.	Milestone	Complete an evaluation of public and professional opinions about the HTA (to inform strategy) by end of Q2. <i>This will be supplemented by an outcome measure when the evaluation criteria have been specified.</i>																						
<b>3. Be informed, influential and active in the environment in which we operate</b> (a) To develop more effective horizon-scanning and knowledge management arrangements (b) To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with the five licensable sectors (c) To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with consent and organ donation (d) To contribute to the development and review of relevant legislation.																											
3.1	b	Res	To develop the licence fees structure for 2011/12.	Milestones	Consult licence fee payers and other interested parties about proposals by end of Q1. Communicate licence fees structure by end of Q2.																						
<b>4. Have motivated and dedicated staff with the right skills in the right jobs</b> (a) To recruit, lead and motivate staff to deliver high quality work (b) To deliver a high quality learning and development programme (c) To develop an environment and culture which encourages continuous improvement and upholds the organisation's values																											
4.1	a	CEO	To implement targeted retention initiatives to maintain the annual attrition rate at 18%.	Measure	Attrition rate (measured monthly on rolling annual basis). Target rate 18%.																						
<b>5. Continuously improve the way the HTA is governed and managed</b> (a) To further develop governance arrangements (b) To continuously review systems, processes and procedures to find ways of working more economically, efficiently and effectively (c) To ensure the continued financial viability of the HTA																											
5.1	a/b	Regs Pol	To extend the HTA's publication scheme under the Freedom of Information Act to improve organisational transparency and accountability.	Milestone	Project plan for publication of significant regulatory action, licensing status and inspection reports developed by end of Q1.																						
5.2	c	Res	To manage the HTA's finances to ensure: sufficient funds in place to meet payments required; appropriate spending; and appropriate levels of reserves.	Measure	Reserves held are within 5% of planned level (Measured monthly).																						