

## Forty first Meeting of the Human Tissue Authority

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**Date** 26 January 2010  
**Time** 10.30am – 1.00pm  
**Venue** HTA Boardroom  
15 – 17 Furnival Street  
London  
EC4A 1AB

### Agenda

(I) = for information; (D) = for decision

1. Welcome and apologies
2. Declarations of interest
3. Minutes of 24 November 2009 HTA (01/10)
4. Matters arising
5. Chair's report Oral
6. Strategic performance review December 2009 HTA (02/10) AMS  
(I)
7. Financial report December 2009 (I) HTA (03/10) SM
8. HTA Strategic Plan 2010-13 and Budget and Strategic Performance Review 2010-11 (D) HTA (04/10) VC & SM
9. Significant regulatory action report 1 October – 31 December 2009 (I) HTA (05/10) AM
10. Regulatory Enforcement and Sanctions Act 2008 (D) HTA (06/10) AM
11. The provision of professional expertise to the Authority (I) HTA (07/10) AM
12. Any other business



## Minutes of the fortieth meeting of the Human Tissue Authority

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**Date** 24 November 2009

**Venue** HTA Boardroom  
15 – 17 Furnival Street  
London  
EC4A 1AB

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<b>Present</b>	
<b>Members</b> Ms Shirley Harrison (Chair) Professor Michael Banner Mrs Jodi Berg Dr Kate Robson-Brown Mr Brian Coulter Professor Ceri Davies Mrs Pamela Goldberg Ms Ruth Musson Dr Andrew Reid Ms Catharine Seddon Ms Helen Shaw	<b>In attendance</b> Mr Adrian McNeil (Chief Executive) Ms Vicki Chapman (Director of Policy and Strategy) Mrs Sue Martin (Director of Resources) Dr Sandy Mather (Director of Regulation) Mr Allan Marriott-Smith (Authority Secretary)
	<b>Observers</b> Mr Peter Jones (Department of Health) Miss Victoria Marshment (Policy Manager)

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Item	Title	Action
<b>Item 1</b>	<b>Welcome and apologies</b>	
	1. The Chair welcomed Members, attendees and observers to the fortieth meeting of the Human Tissue Authority. 2. Apologies were received from Mr Keith Rigg.	
<b>Item 2</b>	<b>Declarations of interest</b>	
	3. There were no declarations of interest.	
<b>Item 3</b>	<b>Minutes of 20 October [paper: HTA (41/09)]</b>	
	4. The minutes were adopted.	
<b>Item 4</b>	<b>Matters arising</b>	
	5. There were updates on several matters arising from previous minutes: <ul style="list-style-type: none"> <li>i. The move to premises in Buckingham Palace Road has been delayed and is now more likely to take place in the latter half of 2010. The HTA is in discussion with the Government Actuary's Department to secure the current accommodation until this time.</li> <li>ii. There were no further developments to report on the University Hospital Wales case since its referral to the Police.</li> <li>iii. The recruitment exercise for new Members is on target for appointments to be made by 1 April 2010.</li> <li>iv. The business case for a rebate to licence fee payers in 2010/11 has been submitted to the Department of Health who are seeking HM Treasury approval for the proposal.</li> </ul>	
<b>Item 5</b>	<b>Chair's report</b>	
	6. The next public meeting of the Authority will be on 23 March and will take place in York. A stakeholder engagement event will be planned to take place in Northern Ireland in the next financial year. 7. The post mortem sector conference took place on 21 October. 191 delegates were in attendance (excluding Members and HTA staff). Evaluation questionnaire from the event showed that the majority of respondents found the event useful and relevant to them. The Chair subsequently received correspondence from the Coroners' Society of England and Wales expressing dissatisfaction with the	

	<p>conference, to which she has made a full response.</p> <p>8. The Chair had attended events in connection with National pathology week (2-8 November) and the organ donation campaign launch by NHSBT on 28 October.</p> <p>9. The Chair noted that this would be her last Authority meeting prior to standing down. She paid tribute to the collective achievement of Members during her time as Chair.</p>	
<b>Item 6</b>	<b>Strategic performance review October 2009 [paper: HTA (42/09)]</b>	
	<p>10. Allan Marriott-Smith introduced the paper and the Strategic Performance Review document for October 2009.</p> <p>11. Members noted the progress against Key Performance Indicators (KPIs). They welcomed the proposal to monitor a KPI measuring staff attrition rates over time, while recognising that this indicator has a number of limitations at this stage of the HTA's organisational development.</p>	
<b>Item 7</b>	<b>Financial report [paper: HTA (43/09)]</b>	
	<p>12. Sue Martin introduced the paper. The Authority were asked to note the following points:</p> <ul style="list-style-type: none"> <li>i. The latest estimate for the revenue position to year end is for a surplus of £570k. This surplus will contribute to estimated reserves of £1.97m at year end.</li> <li>ii. Since the paper was written, the debtor position has improved further to a balance of just over £500k.</li> <li>iii. Not all of the year's capital budget will be spent due to the delay in the office move. The HTA is in discussion with the Department of Health regarding capital funding for an office move in the next financial year.</li> <li>iv. The Grant in Aid (GIA) settlement for the HTA has been agreed for 2010/11, approximately a 3.5% reduction on the previous year.</li> </ul> <p>13. In discussion, Members received two clarifications on the content of the financial report:</p> <ul style="list-style-type: none"> <li>i. The variance in recruitment costs is the result of several factors, including the need to rerun recruitment exercises where no suitable candidates are found. Attrition is less of an influence than it has been historically.</li> <li>ii. One of the causes of debt being unrecoverable is in cases where organisations go into administration. In these cases the HTA are in the same position as other unsecured creditors in relation to claims on a debtor's assets.</li> </ul>	

<b>Item 8</b>	<b>Feedback from the Audit Committee [paper: HTA (44/09)]</b>	
	<p>14. Michael Banner provided a summary of the business from the Audit Committee meeting held on 3 November.</p> <p>15. The Committee had undertaken an initial review of the recently completed Strategic Risk Register. It will continue to monitor the Register in the coming months and will report more fully to the Authority on strategic risk in 2010.</p>	
<b>Item 9</b>	<b>The collection and use of feedback from site visit inspections [paper: HTA (45/09)]</b>	
	<p>16. Sandy Mather introduced the paper. The Authority were asked to note that:</p> <ul style="list-style-type: none"> <li>i. Feedback from site visit inspections provides an important contribution to continuous improvement in the HTA's regulatory activities.</li> <li>ii. The HTA continues to seek ways of improving the quality of the information gathered, including the levels of response to post-inspection questionnaires, to further improve the data's potential.</li> <li>iii. The results should give Authority Members assurance that the inspection process is robust and delivered professionally.</li> </ul> <p>17. Authority Members welcomed the report and proposed a number of avenues which might be explored to improve the quality and potential of the data. These included analysis of characteristics of establishments providing feedback to assess bias in the results, structured telephone interviews as an alternative to questionnaires and seeking feedback at different stages of the inspection process.</p> <p><b>Action:</b> The benefits and feasibility of Members' proposals to improve the feedback from site visit inspections will be assessed further.</p>	SJM
<b>Item 10</b>	<b>Significant regulatory action report 1 July – 30 September 2009 [paper: HTA (46/09)]</b>	
	<p>18. Sandy Mather introduced the paper which is a regular quarterly report to provide Members with an overview of significant regulatory action.</p> <p>19. Members noted the contents of the report.</p>	
<b>Item 11</b>	<b>Regulatory strategy to improve compliance in the post mortem (PM) sector [paper: HTA (47/09)]</b>	

	<p>20. Sandy Mather introduced the paper, which provides the Authority with assurance that a strategy and plans are in place to improve compliance in the post-mortem sector.</p> <p>21. The Authority reviewed the strategy and explored the relative strengths of the regulatory tools which could be deployed in the sector. In particular it considered the balance of site visit inspections and other regulatory tools such as the issue of General Directions to require data collection, including audits as methods of improving regulatory compliance.</p> <p>22. Subject to a small number of drafting changes, the Authority agreed the two-year strategy to improve compliance in the post-mortem sector.</p> <p>23. The Authority considered communication issues associated with the strategy. The following points were raised during the discussion:</p> <ul style="list-style-type: none"> <li>i. In addition to communications directly with licensed establishments, the HTA should work with DH to communicate the strategy and its benefits through influential third parties, such as Strategic Health Authorities and Primary Care Trusts, within the NHS management structure. Hospital trusts should be encouraged to consider regulatory matters, especially in the post mortem and human application sectors, as part of their risk assessment and management.</li> <li>ii. The HTA should work with the Royal College of Pathologists to identify opportunities to produce articles for pathology journals.</li> <li>iii. The HTA should adopt a proactive approach with the media and attempt to make better use of excellent practice as a basis for media stories at a local level.</li> <li>iv. There should be continued attempts to counteract the misconceptions of those who oppose regulation of the sector using factually accurate data and evidence gathered from our experience of regulating.</li> </ul> <p><b>Action:</b> The regulatory strategy for the post-mortem sector will be finalised in light of the Authority’s comments.</p> <p><b>Action:</b> A plan will be developed to communicate the regulatory strategy for the post-mortem sector to stakeholder groups.</p>	<p>SJM</p> <p>SJM/SG</p>
<p><b>Item 12</b></p>	<p><b>Policy on complaints about maladministration by the HTA [paper: HTA (48/09)]</b></p>	
	<p>24. Adrian McNeil introduced the paper which had been produced with contributions from Jodi Berg and Brian</p>	

	<p>Coulter. A number of points were made in discussion:</p> <ul style="list-style-type: none"> <li>i. The Complaints Officer role will eventually be undertaken by the Quality Manager post-holder. In the interim, the role is being fulfilled by the Executive Assistant to the CEO who is also developing the Standard Operating Procedure (SOP).</li> <li>ii. The SOP will make clear the process and associated communication required to close each stage of the complaints process, including those received by telephone. This is to ensure an audit trail is in place should the complainant wish to pursue the complaint further.</li> <li>iii. Prior to being adopted, the SOP will be tested with a variety of scenarios to ensure it is robust.</li> <li>iv. Further work will need to be undertaken on the principle and practice of ex-gratia payments.</li> </ul> <p><b>Action:</b> The policy on complaints, and the associated SOP, will be finalised in light of the Authority's comments.</p>	AM
<b>Item 13</b>	<b>Amendments to Standing Orders [paper: HTA (49/09)]</b>	
	<p>25. Allan Marriott-Smith introduced the paper.</p> <p>26. The Authority agreed that the changes to Standing Orders described in the paper be adopted.</p> <p><b>Action:</b> Revised Standing Orders to be published on the HTA website.</p>	AMS
<b>Item 14</b>	<b>Any other business</b>	
	<p>27. The Authority expressed its gratitude for the leadership provided by Shirley Harrison during her tenure as Chair and wished her every success in future endeavours.</p>	

The meeting closed at 12.30 pm

## Authority paper

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<b>Date</b>	26 January 2010	<b>Paper reference</b>	HTA (02/10)
<b>Agenda item</b>	6	<b>Author</b>	Allan Marriott-Smith

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## Strategic Performance Review – December 2009

### Purpose of paper

1. To inform Members of progress against key performance indicators (KPIs) during December. Members are asked to note the contents of the report.

### Background

2. The Authority has agreed to monitor a set of KPIs that demonstrate whether the HTA's strategic aims are being delivered. Members have previously asked to receive more detailed briefing on remedial action being taken on objectives where the traffic light is showing either red or amber.

### Strategic Performance Review of KPIs – Highlights December

3. The KPI relating to six inspections per quarter for each Regulation Manager (RM) is red. Six RMs did not undertake this number of inspections in Q3 (October to December). This was an intentional change to the inspection schedule to allow a number of RMs to participate in business planning activity for 2010/11 and ensure this was completed to the required timetable.
4. The KPI relating to application of all appropriate sanctions for regulatory non-compliances is red. Outturn was 86% in September relative to a target of 90%. This is due to three post inspection processes (out of 21) being completed outside the 63 day target period. The processes in these three cases were actually completed 13 days late on average and were more complicated cases being undertaken by newer Regulation Managers. As previously identified, these are relatively small base numbers, where each single case represents 9% of the outturn.

5. The KPI for compliance assessments of licence conditions within 28 days is red in November, with an outturn of 66% relative to a target of 90%. This is was a result of the loss of working days over the Christmas break. All relevant licence conditions were compliance assessed in early January.
6. As previously reported, the KPI for producing an updated stakeholder map remains amber, reflecting the agreement to complete in Q4 as opposed to Q3.
7. The KPI for completing a quality audit report for communication activities moves to amber, based on a decision to reschedule this work for Q4.

#### **Outlook for KPIs for the remainder of the year**

8. The KPI relating to six inspections per quarter for each Regulation Manager will not be met in Q4. This is a result of a planned alteration to the inspection schedule to allow data migration from existing licensing systems to the new Customer Relationship Management (CRM) system.

#### **Attrition rate**

9. The rolling twelve-monthly average staff attrition rate is 23%, compared with 23% reported last month.

**Strategic Performance Review - December 2009**

Implement human tissue legislation in a way that promotes safe and ethical practice and is conducted in accordance with the wishes of the individual.																	
Objective	2009/10 High level activity	Business plan activity to be measured	Directorate	Key performance indicators	Delivery update												Comment
					A	M	J	J	A	S	O	N	D	J	F	M	
1. Interpret and implement the principles embodied in the HT Act, EUTCD, and any future relevant European legislation.	Apply all appropriate licensing, inspection, enforcement and regulatory tools to ensure establishments are licensed in accordance with domestic and European legislation.	Implement a risk based schedule of inspections.	Reg	Each competent regulation manager to participate in an average of six inspections per quarter over the year in accordance with standard operating procedures, working instructions and associated quality guidance.	G	G	G	G	G	G	G	G	R			(Sep) Met (Oct) On target for end of the quarter. (Dec) Six RMs did not achieve six inspections per quarter.	
			Reg	All inspection reports are proportionate and evidence based, and at least 90% are issued to Designated Individual and Licence Holder within 28 days of phase two inspections.	R	R	A	G	G	G	R	R	G			(Sep) Outturn for Aug 93%. (Oct) Outturn for Sep 82% (Nov) Outturn for Oct 81% (Dec) Outturn for Nov 95%	
			Reg	Appropriate sanctions are applied for all regulatory non-compliances and at least 90% of them are issued within 63 days of phase two inspections.	R	G	A	G	G	G	R	R	R			(Sep) 93% applied within 63 days. (Oct) 85% applied within 63 days. (Nov) 88% applied within 63 days. (Dec) 86% applied within 63 days.	
			Reg	Written feedback about the inspection process is analysed and key themes with remedial quality improvement measures are reported to the Authority twice a year.	A	A	A	G	G	G	G	G	G			(Sep) Report will be presented to Authority at their November meeting. (Oct) Report will be presented to Authority at their November meeting. (Nov) Report taken to Authority in November. (Dec) Report presented to governance Meeting in January.	
	Apply regulatory enforcement policy.	Reg	90% of licence conditions are compliance assessed within 28 days of the condition deadline and appropriate enforcement action is taken for non compliance.	R	G	A	R	G	G	G	G	R			(Sep) Outturn for August 100% (Oct) Outturn for September 91% (Nov) Outturn for October 94% (Dec) Outturn for November 66%		
Regulate living organ donation.	Reaccreditation of all IA and AA.	Pol	Reaccreditation completed by end Q4.	G	G	G	G	G	G	G	G	G			(Dec) IA and AA reaccreditation will be complete by end March. Work commences in January.		
<b>Maintain the confidence of the public and professionals and continue to work in partnership with them.</b>																	
2. Operate our regulatory framework in a way that gives confidence to professionals and the public.	Work with internal and external stakeholders and other regulators to ensure clarity of roles and strategic purpose.	Review stakeholders in patient groups, private and other 'cross-cutting' sectors and develop a programme for engagement.	Comms Pol	Produce updated stakeholder map by Q3.	A	G	G	G	G	G	A	A	A			(Apr) Amber as we plan to complete in Q3 when we have more staff resources. (May) SMT agreed to change target from Q2 to Q3 resulting from staff shortage. (Oct) This project is likely to run into Q4	
	Evaluate the impact of human tissue legislation on our stakeholders.	Create better understanding of the impact of HT legislation and regulation on the research community and communicate findings to sector and DH.	Comms	Launch research evaluation report by Q2.	G	G	G	G	G	B	B	B	B	B	B		

**Strategic Performance Review - December 2009**

Maintain the confidence of the public and professionals and continue to work in partnership with them.																	
Objective	2009/10 High level activity	Business plan activity to be measured	Directorate	Key performance indicators	Delivery update												Comment
					A	M	J	J	A	S	O	N	D	J	F	M	
3. Engage, consult, communicate and work with our stakeholders to help refine our advice and guidance, standards and regulatory methods.	Improve and refine our communications materials and routes.	Conduct audit of HTA communication activities, advice and guidance meetings and events to inform comms strategy and produce quality audit report informing new communications strategy and future direction.	Comms	Quality audit report produced Q3.	G	G	G	G	G	G	G	G	A				(Dec) This project will take place in Q4
Be recognised as an organisation that makes the best use of the knowledge and information it holds.																	
4. Make best use of knowledge and quality management systems and processes and provide a responsive service to internal and external stakeholders.	Review and refine our Information Management Platform and Communications Tool (IMPACT).	Conduct audit of organisational policies and procedures in each directorate.	Res	All directorates' policies and SOPs have been reviewed to ensure they are proportionate, consistent, clear, minimise resource inputs and are available in IMPACT Q2.	G	G	G	A	A	A	A	A	A			(Sep) Resourcing and timescale to be considered by new DoR as part of overall review of Resources Directorate structure and workplan. (Oct) Recruitment required to support work. Now looking to complete in Q4 (Nov) Recruitment of Quality Manager about to start. (Dec) Quality Manager role advertised	
		New enquiries log and system fully developed and all staff trained to use it.	Comms	New enquiries log and system launched Q1. All staff trained to use new system Q1.	G	G	B	B	B	B	B	B	B	B	B	B	(Apr) In April, pilot training sessions launched. (May) Formally launched on 14 May 2009.
Ensure that the HTA is a distinctive dynamic organisation that people want to work for.																	
5. Create an organisation with a strong corporate culture.	Implement the HTA's HR strategy.	Complete values exercise with staff and Authority and establish baseline for awareness.	CEO	Publish revised HTA values in Q3.	G	G	G	G	G	G	B	B	B	B	B	(Sep) Revised values to be launched at the all staff awayday in October.	
G																	
6. Find the most economical, efficient and effective ways of delivering the service.	Implement new licensing and inspection IT platform.	Run LMS / enquiries / contacts database in parallel with CRM (Q4).	Res		G	G	G	A	G	G	G	G	G			(Sep) R2 work continues to be on time and under budget. (Nov) R2 work completed slightly late but within budget and will not delay next release. Resources both internal and external are scheduled for next stage of project (Dec) R3 and R4 work progressing to schedule. Remaining items scheduled for completion during Jan/Feb	
		Fully implement CRM, with full LMS, enquiries, contacts and calendar functionality – as identified in the project requirements document.	Res	CRM fully implemented Q4.	G	G	A	A	G	G	G	G	G			(Sep) R2 work continues to be on time and under budget. (Nov) R2 work completed slightly late but within budget and will not delay next release. Resources both internal and external are scheduled for next stage of project (Dec) R3 and R4 work progressing to schedule. Remaining items scheduled for completion during Jan/Feb	
		Comply with DH Gateway requirements by submitting our national communications to Gateway for approval.	Comms		G	G	G	G	G	G	G	G	G			(Sept) Nothing required approval during September (Oct) Nothing required approval during October (Nov) Nothing required approval during November (Dec) Nothing required approval during December	



## Authority paper

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<b>Date</b>	14 January 2010	<b>Paper reference</b>	HTA (03/10)
<b>Agenda item</b>	7	<b>Author</b>	Sue Martin

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## Financial report – 2009/10

### Introduction

1. This report provides an update of the HTA's financial position as at 31 December 2009, i.e. after nine months of the financial year.
2. The report provides commentary on the following areas:
  - overview of financial position to 31 December 2009
  - income and expenditure variances
  - other key performance indicators
  - forecast outturn for 2009/10
  - financial risks

### Overview of financial position at 31 December 2009

3. In the first nine months of the year there have been no budgetary issues that have caused SMT any particular concerns.
4. It is anticipated that by 31 March 2010, the majority of the approved posts in the HTA's business case will be filled. Vacancies in the first half of year have led to an underspend on permanent staff.
5. Regular monthly meetings continue to be held with Directors and their budget managers. The current position and forecast outturn on each budget line is reviewed and any necessary virements agreed. After these meetings have been held each month, SMT review the overall position.
6. The forecast of the outturn at year-end has again been reviewed in some detail and is reflected in this report.

### Income and expenditure variances

7. **Annex A** shows the summarised financial position for the year to 31 December 2009. At that date, there was an underspend on revenue expenditure of **£452k** and **£358k** less income than anticipated. Together these resulted in a net surplus on the profiled budget of **£94k** before organisational development costs were taken into account.
8. Expenditure to date on the organisational development budget was **£196k** against the budget profile of **£321k**. Activity relating to organisational change has slowed down and any further costs relating to this are expected to be minimal.

#### ***Income – variances to 31 December 2009***

9. **Annex B** provides a more detailed breakdown of income generated to 31 December 2009. The overall variance of **£358k** relates predominantly to revenue Grant-in-aid (GIA) and licence fee income in all sectors except human application and public display.
10. Revenue Grant-in-aid of **£453k** has been drawn down to date. A further drawdown of £450k which was budgeted for in December is expected to be received in January 2010.
11. Capital GIA of £468k was received in December (£70k had previously been received in April). Expenditure to date has been on the design and implementation work on the HTA's Customer Relationship Management (CRM) system which will be in place by March 2010. A summary of capital income and expenditure information is included in Annex A.

#### ***Expenditure – variances to 31 December 2009***

12. **Annex C** shows expenditure as at 31 December 2009 for staff and non-staff costs. There is an overall underspend of **£577k** against the budget profile. Ignoring 'one off' organisational development costs, there is an underspend currently on staff and non-pay costs of **£452k**. This arises largely from posts being vacant, and uncertainty over the timing of recruitment to posts has made accurate budget profiling difficult. Variances also arise where assumptions about costs and timing of spend is out of alignment with the budget profiles estimated by budget managers.
13. The main variances are summarised below:

<b>Expenditure Variances</b>		
	<b>£</b>	<b>Notes</b>
<b>Staff costs</b>	<b>373,034</b>	This reflects the lag in recruitment this year, vacant posts and uncertainty at budget setting time.
<b>Non staff costs</b>	<b>78,753</b>	<b><i>This variance is analysed in greater detail in the lines below</i></b>
Recruitment	(113,213)	Recruitment costs have been higher than anticipated due to organisational change and the need to run more campaigns than expected.
Training	101,248	Largely due to less competency training than provided for taking place, although corporate training is taking place.
IT and Telecoms	(18,127)	This variance arises from late identification of a pre-payment made last year and the cost of work to extract additional data from LMS.
Conferences and Projects	68,283	There have been fewer events than expected.
Consultancy	35,602	This variance has arisen from profiling issues.
Postage and stationary	31,409	GAD are not charging separately for postage, as had been expected.
Non cash costs	(56,115)	This is an increase in bad debt provision, for writing off debts where establishments are not expected to pay (due to them ceasing trading etc).
Capital Charges	38,427	Assumptions about capital charges have been overtaken by the calculation of actual charges as capital spend has occurred.

**Annex D** provides an analysis of expenditure by Directorate.

## **Other key performance indicators**

### ***Debtors***

14. The debtor position at the end of December was **£212k**. This relates to outstanding licence fee income. This figure has significantly reduced (by £256k) from last month following debt recovery action. Around **£67k** of licence fees invoiced are no longer due, because of changes in the status of establishments, and the HTA will issue credit notes.
15. A further **£73k** of debt is likely to be written off where the organisation has either ceased to trade or are in the process of closing down. The remaining debt of **£72k** (8 establishments) is actively being pursued. **£28k**, which relates to one establishment, was received early in January 2010.
16. Of the £44k still to be recovered, 14% is due from public sector bodies and 85% from private sector bodies (£6.2k public sector and £37.6k private sector). There are 7 establishments included – 2 public bodies and 5 private organisations.

### ***Reserves***

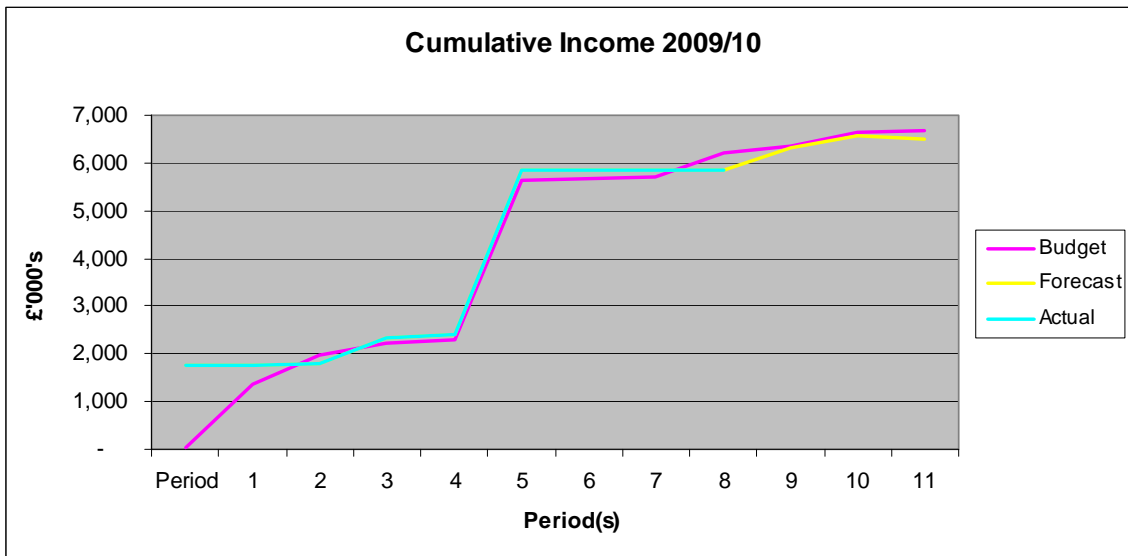
17. The cash balance at the end of December was **£3.0m**. The cash forecast at the end of the financial year is **£2.3m**, from which any rebates would be paid. These cash balances derive from a surplus of income from licence fees.

### **Forecast outturn for 2009/10**

18. The HTA budgeted for a 'break-even' budget this financial year. However, the attached annexes show that a surplus of around **£362k** is considered likely.
19. The planned office relocation will not take place in 2009/10, so the original capital budget will not all be required, as shown in Annex A. We have excluded unused capital funds from the cash reserves, as we will need to agree their treatment with the Department of Health.

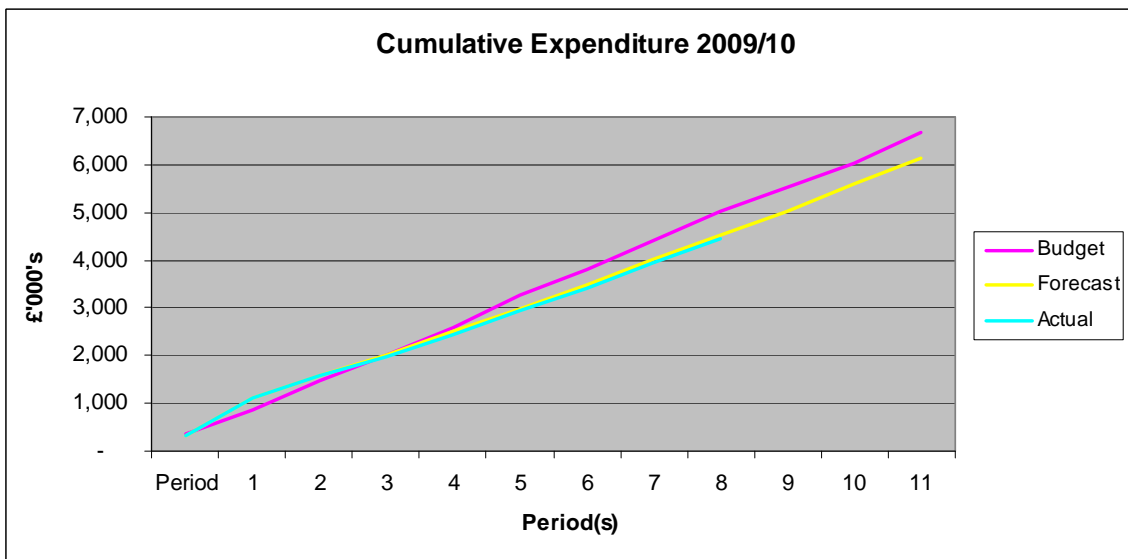
### ***Income***

20. Income for the year is expected to be **£158k** lower than budgeted. This is due to changes in the profile of establishments and some ceasing to trade. The credit notes expected to be issued are now reflected in the forecast income. The graph below details the cumulative budgeted, actual and forecast income for 2009/10.



**Expenditure**

21. The graph below shows the HTA's latest cumulative budgeted, actual and forecast expenditure for the financial year. It shows that at year-end, actual expenditure will be **£333k** less than planned.



**Financial risk**

22. Financial risks that could arise in the future continue to be reviewed on an ongoing basis. Below is a table of the potential risks identified and the mitigating actions and controls taken to minimise them. The financial risks in this summary are linked to one or more of the five high level strategic risks that SMT have identified and are managing.

**Financial Risks**

<b>Risk</b>	<b>Link to the HTA's strategic risks</b>	<b>Mitigating actions and controls</b>
The HTA is required to undertake additional functions or activities not planned or costed within the approved budget.	Insufficient financial resources  Inability to carry out its statutory remit	The HTA's financial management and governance arrangements will be used to identify any opportunities that may arise to offset budgetary pressures and vire monies from elsewhere to fund any such initiatives.
Lack of prompt payment by licence fee payers affects cash flow and operations generally adversely.	Insufficient financial resources	Revenue collection will be closely monitored and the HTA's credit control and debt collection procedures used to pursue and recover all late payments.
Establishments change their profile resulting in a reduction in both hubs and satellites.	Failure to manage change	HTA undertake a periodic review of establishments and track changes to the number of hubs and satellites regularly.
Organisation development and other one-off project costs exceed the budgeted figures and require funding from reserves.	Insufficient financial resources  Failure to manage change	Costs will be closely monitored and the HTA's financial management and governance arrangements will be used to identify any opportunities that may arise to offset budgetary pressures.
Some funding for the HTA's office relocation could be lost if the implementation of this spans two financial years.	Failure to manage change  Inability to react to a major event	The HTA is in ongoing discussions with DH Estates, who are leading on progress with the new office, to seek greater clarity about funding for the move in 2010/11.
Repercussions on the HTA resulting from the submission of a business case to HMT for approval to the	Inadequate relationship management	Submission of an informative and reasoned business case for making a licence fee rebate to establishments (deemed to be special

<b>Risk</b>	<b>Link to the HTA's strategic risks</b>	<b>Mitigating actions and controls</b>
licence fee rebate in 2010/11.		payment) that is supported by DH that results in approval by HMT.
A significant under-spend leading to a loss of stakeholder confidence in HTA's ability to budget and manage resources effectively.	Inadequate relationship management	Regular monitoring of the annual budget by SMT and budget managers throughout the financial year with realistic forecasts of the likely outturn from as early as possible.

### **Conclusion**

23. The Authority is asked to note the financial position as at 31 December 2009.

# Human Tissue Authority

## Summary - Income & Expenditure

Annex A

December 2009 (Month 9)

Table 1 - Income & Expenditure Summary

Income & Expenditure	Year to Date			Full Year			
	Actual £	Budget £	Variance £	F'cast £	Budget £	Variance £	%
<b>Total Income</b>	5,862,344	6,220,570	(358,227)	6,503,994	6,661,750	(157,756)	-2.4%
<b>Less:</b>							
<b>Total Revenue Expenditure</b>	(4,244,402)	(4,696,189)	451,787	(5,924,221)	(6,229,313)	305,093	4.9%
<b>Gross Surplus/(Deficit)</b>	1,617,942	1,524,381	93,561	579,773	432,437	147,337	
<b>Extraordinary Items</b>							
Organisational Dev/Project costs and Contingency	(196,246)	(321,739)	125,493	(217,285)	(432,437)	215,152	50%
<b>Net Income &amp; Expenditure Revenue Surplus</b>	<b>1,421,696</b>	<b>1,202,642</b>	<b>219,054</b>	<b>362,488</b>	<b>(0)</b>	<b>362,489</b>	

Table 1.1 - Capital Expenditure Summary

Capital	Year to Date			Full Year			
	Actual £	Budget £	Variance £	F'cast £	Budget £	Variance £	
<b>Capital grant in aid</b>	538,000	538,000	0	810,000	1,310,000	(500,000)	-38%
<b>Less:</b>							
<b>Total Capital Expenditure</b>	(621,195)	(404,339)	(216,856)	(810,000)	(1,310,000)	500,000	-38%
<b>Net Capital Surplus / (Deficit)</b>	<b>(83,195)</b>	<b>133,661</b>	<b>(216,856)</b>	<b>(0)</b>	<b>0</b>	<b>(0)</b>	<b>0%</b>

# Human Tissue Authority

## Income Summary

Annex B

December 2009 (Month 9)

Table 2 - Income Summary

Income Summary (excluding Capital)	Year to Date				Full Year Forecast			
	Actual	Budget	Variance <sup>1</sup>		F'cast	Budget	Variance	
	£	£	£	%	£	£	£	%
<b>Grant In Aid</b>								
GIA	453,000	903,000	(450,000)	0%	1,133,000	1,133,000	0	0%
<b>Sub-Total</b>	<b>453,000</b>	<b>903,000</b>	<b>(450,000)</b>	-50%	<b>1,133,000</b>	<b>1,133,000</b>	<b>0</b>	0%
<b>Licence Fees</b>								
Anatomy	247,925	220,049	27,876	13%	247,925	220,900	27,025	12%
Post Mortem	1,896,100	1,864,007	32,093	2%	1,896,100	1,935,600	(39,500)	(2)%
Public Display	42,430	58,072	(15,642)	-27%	41,430	58,880	(17,450)	(30)%
Research	953,700	933,700	20,000	2%	947,700	987,300	(39,600)	(4)%
Human application	2,161,400	2,196,721	(35,321)	-2%	2,100,600	2,254,200	(153,600)	(7)%
<b>Sub-Total</b>	<b>5,301,555</b>	<b>5,272,549</b>	<b>29,006</b>	1%	<b>5,233,755</b>	<b>5,456,880</b>	<b>(223,125)</b>	(4)%
<b>Other</b>								
Other income	8,600	450	8,150	1812%	10,150	2,000	8,150	408%
Scottish & N. Ireland Execs. & Welsh Assembly	99,189	44,572	54,617	123%	127,089	69,870	57,219	82%
<b>Sub-Total</b>	<b>107,789</b>	<b>45,021</b>	<b>62,767</b>	139%	<b>137,239</b>	<b>71,870</b>	<b>65,369</b>	91%
<b>Total Income</b>	<b>5,862,344</b>	<b>6,220,570</b>	<b>(358,227)</b>	-6%	<b>6,503,994</b>	<b>6,661,750</b>	<b>(157,756)</b>	(2)%

Note 1: ( ) = under-recovery of income

# Human Tissue Authority

## Expenditure Summary

Annex C

December 2009 (Month 9)

Table 3 - Expenditure Summary

Expenditure Summary	Year to Date			Full Year			
	Actual £	Budget £	Variance <sup>1</sup> £	F'cast £	Budget £	Variance £	%
Staff Costs	2,373,528	2,746,562	373,034	3,307,251	3,682,542	375,290	10%
Non Staff Costs	1,870,874	1,949,627	78,753	2,616,970	2,546,772	(70,198)	(3)%
<b>Total ordinary activities</b>	<b>4,244,402</b>	<b>4,696,189</b>	<b>451,787</b>	<b>5,924,221</b>	<b>6,229,313</b>	<b>305,093</b>	<b>5%</b>
Organisational Dev costs/Contingency costs	196,246	321,739	125,493	217,285	432,437	215,152	50%
<b>Total Revenue Expenditure</b>	<b>4,440,648</b>	<b>5,017,928</b>	<b>577,280</b>	<b>6,141,506</b>	<b>6,661,750</b>	<b>520,244</b>	<b>9%</b>

Note 1: ( ) = overspend

# Human Tissue Authority

## Directorate Summary

Annex D

December 2009 (Month 9)

Table 4 - Directorate Summary

Directorate Summary	Year to Date				Full Year			
	Actual £	Budget £	Variance <sup>1</sup> £	%	F'cast £	Budget £	Variance £	%
Communications	288,847	406,751	117,904	29%	444,084	521,163	77,079	15%
Regulation	1,296,637	1,444,775	148,138	10%	1,785,695	2,018,900	233,205	12%
Policy	257,853	366,475	108,623	30%	401,197	494,752	93,555	19%
Legal	96,811	114,469	17,658	15%	139,569	163,378	23,810	15%
HTA Board	163,946	233,698	69,753	30%	232,404	291,458	59,054	20%
Resources	1,417,141	1,425,870	8,729	1%	1,896,166	1,805,859	(90,306)	(5)%
Chief Executive's Office	723,168	704,151	(19,018)	-3%	1,025,107	933,803	(91,304)	(10)%
<b>Subtotal</b>	<b>4,244,402</b>	<b>4,696,189</b>	<b>451,787</b>	<b>10%</b>	<b>5,924,221</b>	<b>6,229,313</b>	<b>305,093</b>	<b>5%</b>
Organisational Development/Project costs	196,246	321,739	125,493	39%	217,285	432,437	215,152	50%
<b>Total Resource Expenditure</b>	<b>4,440,648</b>	<b>5,017,928</b>	<b>577,280</b>	<b>12%</b>	<b>6,141,506</b>	<b>6,661,750</b>	<b>520,244</b>	<b>8%</b>

Note 1: ( ) = overspend

## Authority paper

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<b>Date</b>	26 January 2010	<b>Paper reference</b>	HTA (04/10)
<b>Agenda item</b>	8	<b>Author</b>	Sue Martin Vicki Chapman

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## HTA Strategic Plan 2010–13 and Budget and Strategic Performance Review 2010/11

### Purpose of paper

1. To provide the Authority with a final draft of the Strategic Plan for 2010–13 and to give the Authority sight of the budget and Strategic Performance Review for 2010/11, thus providing assurance that plans are in place to deliver year one of the strategic plan.

### Background

2. During the first half of 2009/10, the Authority undertook a series of activities, first in Members' groups and then collectively, to review the strategic issues facing the HTA over the next three years.
3. The Authority agreed a strategic framework, including five high level strategic aims, in July 2009 (paper HTA (24/09)) and discussed an early draft of the Strategic Plan for 2010–13 at its September awayday.

### Strategic Plan 2010–13

4. SMT have developed a set of high level objectives to deliver the strategic aims. These are set out in the Strategic Plan 2010–13 which is attached at Annex A.
5. The plan will be published on the HTA website at the beginning of the next business year.

## **Outline Budget 2010/11**

6. During late 2009, the executive undertook a detailed planning exercise to translate the strategic aims and high level objectives into a set of detailed business activities and objectives for 2010/11. The full detail will eventually translate into the performance development plans of individual staff members. In this way there is a clear link between the strategic aims and what each Directorate, team and individual contributes towards delivering the HTA strategic plan.
7. As part of this planning exercise, the executive has estimated the staff time associated with the delivery of the plan. The staff costs of delivering each of the strategic aims have been calculated and other direct costs associated with specific pieces of work relating to individual aims have been identified. Other non-staff costs for 2010/11 have been estimated and the outline budget for 2010/11 is included in Annex B.
8. Table 1 compares the outline budget to the HTA's expected spend in 2009/10 and shows that we propose a balanced budget for 2010/11. We are also exploring rebating licence fee payers from reserves accumulated in previous years, which would reduce our reserve levels by £700,000. The remaining reserves would be retained throughout 2010/11, providing a prudent reserve as we move to a different licence fee structure in 2011/12. Following the Authority's consideration of the proposed outline budget, we will develop more detailed budgets for 2010/11 and allocate funds to Directorates.
9. Table 2 shows the costs identified in delivering strategic aims. It is a big step forward for the HTA to cost business plans in this way and identify the costs of delivering aims and objectives and we hope that you find this helpful. Some costs have not been allocated to objectives at this stage and we will explore the value of apportioning these for the future. It is important to understand that all of the strategic aims support the regulatory system and licensing activity, so the analysis of expected spend by strategic aim does not correlate to funding provided by grant in aid and licence fees.

## **Strategic Performance Review 2010/11**

10. From the detailed plan, the executive has identified a series of key performance indicators (KPIs) (which will be monitored by the Authority each month in the Strategic Performance Review) and performance indicators (PIs) (which will be monitored by the SMT each month). The KPIs will provide the Authority and Department of Health with high-level assurance that the strategic plan is being delivered, while the PIs provide SMT with assurance about the operational health of the business. Annex C provides the proposed KPIs for 2010/11.

11. The Authority will wish to note that there is a balance to be struck between providing consistency in the KPIs versus improving their quality and relevance. The executive have taken the view that 2009/10 provided some valuable lessons about the quality of performance measures and milestones and that it is better to provide the Authority with better indicators than to retain consistency for its own sake.

### **Action**

12. The Authority is asked to:

- approve the strategic plan for publication on the HTA website
- approve the outline budget for 2010/11
- note the content of the proposed structure of the Strategic Performance Review for 2010/11.

## **Annex A - Strategic Plan 2010-13**

### **Human Tissue Authority – Draft Strategic Plan 2010/11 to 2012/13**

**Introduction from the Chair** – Will be drafted prior to publication.

#### **What we do – our remit**

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 800 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.

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**

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 by fulfilling five strategic aims:

#### **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:

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

## **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:

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

## **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.

The associated objectives for 2010/11 are:

- To develop more effective horizon-scanning and knowledge management arrangements
- To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with the five licensable sectors
- To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with consent and organ donation
- To contribute to the development and review of relevant legislation.

## **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:

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

## **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:

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

**Annex B****Table 1 - Outline Budget 2010/11**

	Notes	2010/11 Budget £000k	As at 31-Dec-09 2009/10 Expected spend £000k	Variance £000k	Variance %
<b>Income:</b>					
DH Funding	1	1,093	1,133	-40	-4%
Licence Fees		5,234	5,234	1	0%
Other Income	2	108	137	-29	-21%
<b>Total Income</b>		<b>6,435</b>	<b>6,504</b>	<b>-69</b>	<b>-1%</b>
<b>Expenditure:</b>					
Staff costs	3	3,840	3,307	533	16%
Travel & subsistence		177	157	19	12%
Training & recruitment	4	353	578	-225	-39%
Conferences & project costs	5	224	179	44	25%
Post, stationery & printing		90	100	-11	-11%
Other costs		42	60	-18	-30%
I.T. & telecommunications	6	280	231	50	21%
Legal & professional		126	138	-12	-8%
Consultancy	7	148	75	73	97%
Accommodation	8	521	516	5	1%
Non cash costs	9	46	110	-64	-58%
<b>Total operating costs</b>		<b>5,846</b>	<b>5,451</b>	<b>395</b>	<b>7%</b>
Organisational Development Costs	10	-	217	-217	-100%
Capital charges	11	589	473	116	25%
<b>Total Revenue Expenditure</b>		<b>6,435</b>	<b>6,142</b>	<b>294</b>	<b>5%</b>

## Notes:

- 1 DH funding has reduced by 3%, in line with government funding constraints
- 2 Other income was higher in 2009/10, as it included two payments from the Scottish Executive
- 3 Staff costs have been calculated on the basis of full staffing and no provision for salary increases. Vacancies will provide some flexibility for any agreed salary increases.
- 4 Training and recruitment costs will be less in 2010/11, with a more experienced workforce
- 5 Conference costs will be greater in 2010/11 due to more face to face training events for DIs and stakeholder workshops
- 6 IT development has been included in this revenue budget for 2010/11 (most could be capitalised in 2009/10)
- 7 Consultancy is required in 2010/11 to support stakeholder engagement, ongoing HR activity (much was met previously from the Organisational Development budget) and complete fees model development

- 8 Accommodation costs are assumed to be at the same level as those incurred presently, throughout the year. The increase in 2010/11 is due to additional, chargeable room hire likely to be required.
- 9 Non cash costs in 2009/10 included the writing off of debts which are not expected to be at the same level in 2010/11
- 10 Organisational development costs were significant in 2009/10 as the HTA grew. Ongoing needs are absorbed into other budgets for 2010/11.
- 11 Capital charges will increase in 2010/11 due to the depreciation costs of IT developments that were capitalised in 2009/10

**Table 2 - Costed Business Plan 2010-11 at summary level**

Strategic Objective	SO1	SO2	SO3	SO4	SO5	Unallocated	Total
<b>Staff Costs</b>							
Staff salaries	1,786,752	465,826	230,944	351,710	429,698	413,074	<b>3,678,003</b>
	49%	13%	6%	10%	12%	11%	
Members Allowance						162,418	<b>162,418</b>
<b>Non staff costs (high level)</b>							
Travel & subsistence	91,200					85,500	176,700
Training & recruitment						353,400	353,400
Conference & project costs		120,000				103,500	223,500
Post, stationery & printing						89,700	89,700
Other costs						41,892	41,892
I.T. & telecommunications						280,422	280,422
Legal & professional						126,000	126,000
Consultancy	65,000			62,500	20,000		147,500
Accommodation						520,756	520,756
Non cash costs						46,000	46,000
Capital charges						589,110	589,110
<b>Total expenditure</b>	<b>1,942,952</b>	<b>585,826</b>	<b>230,944</b>	<b>414,210</b>	<b>449,698</b>	<b>2,811,772</b>	<b>6,435,401</b>



<b>2. Build and develop effective relationships with stakeholders and the public, based on trust</b> <b>(a) To capture and evaluate stakeholder opinion</b> <b>(b) To increase the public awareness of the HTA</b> <b>(c) To manage the reputation of the HTA effectively</b>										
7	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. <b>This will be supplemented by an outcome measure when the evaluation criteria have been specified.</b>					
<b>3. Be informed, influential and active in the environment in which we operate</b> <b>(a) To develop more effective horizon-scanning and knowledge management arrangements</b> <b>(b) To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with the five licensable sectors</b> <b>(c) To engage with key stakeholders to develop forward thinking and planning in key policy issues associated with consent and organ donation</b> <b>(d) To contribute to the development and review of relevant legislation.</b>										
8	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> <b>(a) To recruit, lead and motivate staff to deliver high quality work</b> <b>(b) To deliver a high quality learning and development programme</b> <b>(c) To develop a culture which encourages continuous improvement and upholds the organisation's values</b>										
9	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> <b>(a) To further develop governance arrangements</b> <b>(b) To continuously review systems, processes and procedures to find ways of working more economically, efficiently and effectively</b> <b>(c) To ensure the continued financial viability of the HTA</b>										
10	a/b	Reg 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.					
11	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).					



## Authority paper

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<b>Date</b>	26 January 2010	<b>Paper reference</b>	HTA (05/10)
<b>Agenda item</b>	9	<b>Author</b>	Stephen Wicks

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## Significant regulatory activity report 1 October – 31 December 2009

### Introduction

1. This paper summarises the significant regulatory action taken by the Human Tissue Authority (HTA) Regulation Directorate between 1 October and 31 December 2009. It also summarises, in Appendix 1, the significant regulatory action taken across all the sectors in the year to date. Details of the regulatory enforcement action available to the HTA can be found in the Regulatory Enforcement Policy which is published on the HTA website.

### Section 1: Legal Notices

#### *Special Directions*

2. One set of special directions was issued between 1 October and 31 December 2009.
3. Significant failings had been identified during an inspection site visit of a post mortem sector establishment in Q2 of the business year and the establishment put together an action plan to address these failings. A follow up site visit inspection in Q2 was carried out to review progress against the action plan. Special directions were issued after the follow up site visit inspection requiring the establishment to improve compliance with the HTA standard relating to consent training. In addition the special directions required the establishment to continue to work to its own action plan to maintain compliance with all HTA standards, and provide the HTA with regular written updates.

### ***Notice of refusal to grant a licence***

4. No notices of refusal to grant a licence were issued between 1 October 2009 and 31 December 2009.

### ***Notice of suspension of a licence***

5. One notice of suspension was issued between 1 October and 31 December 2009.
6. The licence held for the procurement, processing, testing, distribution, import and export of tissues and cells was suspended for a period of up to three months for one establishment in the human application sector. This was on the basis of the failure of the Designated Individual (DI) to comply with standards relating to the processing and storage of human tissues and cells. The Authority also ceased to be satisfied that the premises were suitable because of a lack of sufficient environmental controls. The establishment were advised that the suspension may be lifted sooner if the Authority could be assured of the suitability of the practices and premises within a shorter period of time.
7. The establishment was advised that the Authority did take into account that an immediate suspension may affect the reputation of the establishment and had implications for service delivery. The Authority balanced the need for a suspension against the effect it might have and decided that, because of the serious shortfalls found during the inspection and the risk to patients identified above, suspension was a proportionate response.

### ***Notice of revocation of a licence***

8. No notices of revocation of a licence were issued between 1 October and 31 December 2009.

## **Section 2: Regulatory Action Panels**

9. A regulatory action panel (RAP) is convened when significant regulatory action is considered and to assist the decision maker. The aim of the RAP is to provide a robust framework to escalate licensing decisions to ensure a fair, proportionate, justifiable evidence-based decision.
10. The number of RAPs has reduced from 16 in Q1 (April - June 2009) to 11 in Q2 (July - September 2009) and four in Q3 (October – December 2009).

<b>Sector</b>	<b>October – December 2009</b>	<b>Business year total (from April 2009)</b>
<b>Anatomy</b>	0	0
<b>Human application</b>	2	12
<b>Post mortem</b>	0	14
<b>Research</b>	1	1
<b>Public display</b>	0	0
<b>Unlicensed establishments</b>	1	3
<b>Other</b>	0	1
<b>TOTAL</b>	<b>4</b>	<b>31</b>

11. In addition, three cases about establishments in the post mortem sector and two cases about establishments in the human application sector were managed outside the RAP process. Detail about these is given in paragraphs 13-15 below.

***Regulatory issues about establishments in the post-mortem sector***

12. There were no RAPs in the post mortem sector. However, three issues were brought to the attention of the HTA and investigated, details of which are provided below.

13. A whistleblower notified the HTA that a large store of relevant material, including whole fetuses, was being retained and no attempt was being made to dispose of this tissue. On investigation, the HTA established that this store consisted of fetuses which were all pre-13 weeks gestation and were existing holdings. The HTA issued written advice and guidance about disposal of relevant material to the establishment.

14. An establishment contacted the HTA about an adverse event where the wrong body was released to a family. The family were notified prior to burial. The establishment conducted a root cause analysis and identified six contributing factors all of which were related to HTA standards. A routine inspection of this establishment had been conducted in August 2007 and previous areas of non-compliance had been addressed by the establishment. The establishment's

progress against an action plan produced in response to the incident is being monitored and systems of traceability will be looked at as part of an inspection scheduled for a nearby establishment that sends relevant material to the establishment in question for analysis.

15. A DI informed the HTA that a brain had been retained. Upon investigation, it was identified that the post-mortem examination had been conducted before commencement of the HT Act and the establishment did not have any information recording the family's wishes. A routine site visit inspection had already been scheduled and this incident was reviewed on inspection. The inspection team were satisfied with the establishment's response to this incident, the response to the relatives and improvements to prevent a similar incident were satisfactory. The HTA took no significant regulatory action.

### ***Regulatory issues about establishments in the human application sector***

16. Three RAPs were held for two licensed and one unlicensed establishment in the human application sector. Two issues brought to the attention of the HTA were managed outside the RAP process.
17. One RAP resulted in the issue of notice of suspension (*see p2, paragraphs 5-7*).
18. The RAP for the unlicensed establishment was convened after a proposed licence holder refused to acknowledge a licence offer on the basis of the associated licence fee. Confirmation was sought that licensable activities were not being carried out, but no response or acknowledgement was received despite repeated requests. The HTA became concerned that the establishment was continuing to conduct licensable activities not under the authority of a licence. Consideration was given as to whether a referral to the police should be made. The Senior Management Team decided not to make a referral to the police but instead to communicate with relevant end users to notify them of the list of licensed establishments in the UK that it was lawful to accept products from. The establishment subsequently confirmed that it was no longer undertaking licensable activities
19. An establishment failed to pay the full licence fee for this year and as per our standard debtor procedure a RAP was convened, to consider the status of their licence. The HTA decided to engage with the establishment to seek to clarify whether the establishment needs a licence, what implications any revocation may have and if the establishment is now in a position to pay. This process is ongoing.
20. The HTA became aware, via a media article, that a clinical trial was being conducted at several establishments in the UK. The trial involved a processing

technique which had the potential to affect the quality and safety of the cells intended for use for human application. This activity falls outside the HTA's licensing requirements as it is being undertaken as a 'single surgical procedure' so no significant regulatory action was taken. During this investigation, legal advice was sought together with advice from two other EU Member States. A policy paper has been drafted to define the HTA's future response to this type of activity and when activity should not be regarded as a single surgical procedure.

21. An establishment failed to pay the full licence fee amount and failed to advise the HTA of a suitable Licence Holder. The company has now gone into administration and the licence has expired. The HTA established that six samples were still being stored at the establishment and these were transferred to another HTA-licensed establishment. The payment of the licence fees is being pursued as per the HTA's standard debtor procedure.

### ***Regulatory issues about establishments in the research sector***

22. One RAP concerned a DI who had failed to comply with the standard condition on the licence to complete DI training despite repeated requests and warnings from the HTA. The HTA convened a RAP in which it was decided to suspend the RAP to allow time review of legal advice and to look at potential ways for the DI to achieve compliance with this standard condition. This process is ongoing.

## **Section 3: Challenges to licensing decisions**

### ***Representations***

23. The HTA held one Representations Panel between 1 October 2009 and 31 December 2009.
24. Representations were heard about a proposed licensing decision to revoke a licence for the storage of relevant material in the post mortem sector. The grounds for proposing this decision were the unsuitability of the DI in place at the time of the inspection and the failure of the then DI to fulfil the statutory responsibilities under s18 of the Human Tissue Act 2004. In addition the new DI, who was nominated after the site visit inspection, had not yet had the opportunity to discharge the statutory duties under s18 of the Human Tissue Act.
25. The Representations Panel decided not to take the decision to revoke the licence. It was concluded that while the grounds identified for proposing the decision were valid at the time the Notice was issued, these grounds no longer existed due to the appointment of a new DI and improved governance at the establishment. The Panel were satisfied that the new DI is now discharging his statutory duties.

### ***Appeals***

26. The HTA held no appeal hearings between 1 October 2009 and 31 December 2009.

### ***Complaints***

27. The Regulation Directorate received one complaint from a DI about the tone of a letter requesting compliance with the standard condition regarding completion of DI training. The DI in question had failed to complete training to the satisfaction of the HTA within the required 12 months. This final request letter was a standard format but may have been received in isolation because of earlier letters being sent to the wrong address.

28. The matter was handled informally and an apology made. The HTA is considering how we can ensure the DI completes training to our satisfaction and will undertake a review of the process for sending out these letters and the tone of enforcement letters.

### **Conclusion**

29. Members are asked to note the significant regulatory action taken by the HTA.

**APPENDIX 1 - SUMMARY DATA**

	<b>Significant regulatory action 1 Apr – 30 Jun 2009</b>	<b>Significant regulatory action 1 Jul – 30 Sep 2009</b>	<b>Significant regulatory action 1 Oct – 31 Dec 2009</b>
<b>Notice of refusal to grant a licence issued</b>	0	0	0
<b>Notice of suspension of a licence issued</b>	1	2	1
<b>Notice of revocation of a licence issued</b>	0	0	0
<b>Regulatory Action Panels held</b>	16	11	4
<b>Special directions issued</b>	3	3	1
<b>Representations Hearings held</b>	0	0	1
<b>Appeal Hearings held</b>	0	0	0

## Authority paper

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<b>Date</b>	26 January 2010	<b>Paper reference</b>	HTA (06/10)
<b>Agenda item</b>	10	<b>Author</b>	Stephen Wicks

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## Regulatory Enforcement and Sanctions Act 2008

### Purpose of paper

1. To explain the purpose and implications of the Regulatory Enforcement and Sanctions Act 2008 (RES Act) and to seek the Authority's agreement that, for now, the Human Tissue Authority (HTA) should not apply for powers under this Act.

### Background

2. The RES Act came into force in October 2008 and primarily affects national regulators and local authorities. The HTA is included in schedule five of the RES Act as one of the designated regulators to which the legislation could apply.
3. The RES Act follows on from recommendations set out in the Hampton Review 'Reducing Administrative Burdens: Effective Inspection and Enforcement' (2005) and the Macrory Review 'Regulatory Justice: Making Sanctions Effective' (2006). Hampton found that some regulators' penalty regimes were cumbersome and ineffective and recommended that a comprehensive review of these regimes should take place. This review was carried out by Macrory who found that some regulatory sanction regimes were over-reliant on criminal prosecution and lacked flexibility. Consequently, Macrory recommended that regulators be given access to a more flexible set of sanctioning tools.
4. The Authority agreed on 18 November 2008 not to apply for RES Act powers in the 2009/10 business year and to review the situation in one year.

## **The key elements of the RES Act as it applies to the HTA**

5. There are five parts to the RES Act. Part three of the RES Act, which has particular relevance to the HTA, allows for civil sanctions to be applied where a criminal offence has taken place. The four civil sanctions included within this part are summarised in Annex A. There is some duplication of the sanctions currently available to the HTA.
6. A timeline and overview of the process for the HTA to seek RES Act powers is provided at Annex B.

## **Issues for the Authority to consider**

7. There are two main issues to consider:
  - (i) Does the HTA need RES Act powers?
  - (ii) What would be the implications of using them?
8. Many regulators do not have the extensive licensing sanctions that the HTA has under the Human Tissue Act 2004 and the associated Human Tissue (Quality and Safety for Human Application) Regulations 2007. Thus the RES Act powers are designed to provide these regulators with a broader range of more proportionate enforcement sanctions to use in place of criminal prosecutions. The regulatory sanctions that the HTA has at its disposal (and uses extensively) include licence variation, licence revocation, licence suspension (which is immediate) and refusal of a licence. Providing the HTA continues to use these powers robustly and effectively, there is little or no advantage in applying for the additional RES Act powers.
9. Our style and practice, which has been largely successful, and which fits with the principles of better regulation, has been to use the regulatory sanctions already available to achieve compliance. There is a risk, even with infrequent use of the RES Act powers, that the HTA would be seen as being more enforcement orientated and this could result in establishments not coming forward for advice or to volunteer information about shortcomings in their practice.
10. The level of evidence required to take civil action under the RES Act would be much higher than that needed to take regulatory action. In fact, we believe that the burden of proof required for civil action under the RES Act would be similar to that for criminal prosecution. The need for staff to be trained in, and conversant with, enforcement to this much higher level would be justifiable only if we were to use the new powers frequently. But this would be unlikely given

our experience of the effectiveness of the sanctions already available to, and used by, the HTA.

11. There are two phases to the work involved in applying for RES Act powers (see Annex B). The first is to apply for the powers themselves: this would be led by the Department of Health (DH) with input from the HTA. The second is to prepare the people, processes and infrastructure in the HTA to be able to use the RES Act powers, which would be led by the HTA.
12. If the HTA did decide to apply for the RES Act powers, a significant number of systems and processes would need to be introduced. These include IT development, drafting legal enforcement template notices and developing new standard operating procedures that ensure the processes are correctly and consistently applied. The HTA would also have to prepare policies and detailed guidance on sanctions, enforcement action and the circumstances in which these new powers would be used. At a minimum, we would need to train the staff in the licensing and enforcement team on these specialist enforcement skills. If we used the new powers more extensively, it would be necessary to recruit new staff that have specialist enforcement knowledge, skills and experience.
13. The HTA has a pressing work agenda which we would not wish to put at risk by taking on additional work that would divert existing resources and distract staff from delivery of our core remit. It may be difficult to get agreement from the DH to an increase in staffing, should that be necessary, and there could be an increase in running costs that might necessitate an increase in licence fees.
14. Nevertheless, we may find in the future that the use of the current suite of regulatory sanctions available to the HTA may not be sufficient to achieve compliance and that we might then benefit from the additional sanctions available through the RES Act. We propose that the HTA's position is reviewed in two years to see if this is the case.

### **Risks associated with not applying for RES Act powers in 2010**

15. If the HTA decides to defer an application for these powers, there is a risk that Ministers may not be able to satisfy themselves that the HTA is Hampton-compliant (see Annex B) since more than a year will have passed since the Hampton Implementation Review. We think this is a small risk, based on a technicality that is worth taking.

## **Conclusion**

16. Introduction of RES Act powers would entail a considerable amount of additional work and resources that could be justified only if the powers were to be used extensively. This would be highly unlikely given the extensive range of regulatory sanctions already available to, and used by, the HTA.
17. Members are invited to agree that the HTA should not apply for RES Act powers now and should review the position in two years time.

## Annex A

### The key elements of part three of the RES Act as it applies to the HTA

1. There are five parts to the RES Act and part three is of particular relevance to the HTA. Part three allows for civil sanctions to be applied where a criminal offence has taken place. The aim is to avoid the need for regulators to always proceed to criminal prosecution and to use more proportionate sanctions instead.
2. The new RES Act powers are an alternative to criminal prosecution and it is for the regulator to determine the appropriate response to a particular instance of regulatory non-compliance. The sanctions should allow regulators to take more proportionate action. Many regulators do not have the extensive licensing sanctions that are provided within the Human Tissue Act 2004 (HT Act) and the associated Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations).
3. There are four civil sanctions included within part three of the RES Act.
  - (a) **Fixed monetary penalty (FMP) notices.** This is for a maximum of £5,000 and is intended to deal with low-level minor instances of non-compliance for criminal offences.
  - (b) **Discretionary requirements.** This is intended to be for mid- to high-level non-compliances, again for criminal offences. There are three discretionary enforcement options within this. They are:
    - a variable monetary penalty (VMP) determined by the regulator. This is subject to a maximum of £5,000;
    - a requirement to take specified steps within a stated period to secure that an offence does not continue or happen again (compliance notice); and
    - a requirement to take specified steps within a stated period to secure that the position is restored so far as possible to what it would have been if no offence had been committed (restoration notice). This could include, for example, reimbursing a customer's money.
  - (c) **Stop notices.** These should be used where there is a significant risk of serious harm by the criminal offence and should be used with caution. If these are issued inappropriately by the regulator the licensed establishment can seek compensation. Stop notices have immediate impact.

(d) **Enforcement undertakings.** These sanctions will enable a business to give an undertaking voluntarily to the regulator to take one or more corrective actions. The enforcement undertaking is initiated by the establishment themselves and is normally where a regulator reasonably suspects that the establishment has committed a criminal offence.

4. Members should note that any monetary penalties imposed are only payable into a consolidated fund and not directly to an individual regulator.

## **Annex B**

### **Timeline and overview of the process for the HTA to seek RES Act powers**

1. Regulators can apply for these additional enforcement powers following a successful Hampton Implementation Review (HIR). The report of an HIR review should be submitted with the proposal to seek powers under the RES Act. The HIR review must satisfy Ministers that the HTA is Hampton compliant.
2. The report of the HTA HIR review was published by the Better Regulation Executive on 23 July 2009. If the HTA wishes to apply for RES Act powers, we have been advised that this should be done within six months of the HIR review being published. This is so that Ministers can assure themselves that the HTA are compliant at the time of application
3. Once the HTA decides to apply for the powers, the Department of Health (DH) would need to draft a Ministerial Order, which should be supported by a full Regulatory Impact Assessment. DH would need to undertake a full twelve week consultation. Following any amendment after the consultation process the order will be subject to a vote in both Houses of Parliament.
4. If the HTA applies for the RES Act powers then there should be an intention to use those powers when they are issued. The Department of Business, Enterprise and Regulatory Reform have advised that Ministers would not look favourably on a regulator who applied for the RES Act powers as a 'future proofing' mechanism.
5. The HTA would need to apply for the RES Act powers in April 2010 and the process is likely to take a minimum of six months. Concurrently to this, the HTA would need to be developing associated formal notices, standard operating procedures and develop IT systems to align with existing processes to allow the use of the RES Act powers.

## Authority paper

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<b>Date</b>	26 January 2010	<b>Paper reference</b>	HTA (07/10)
<b>Agenda item</b>	11	<b>Author</b>	Adrian McNeil

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## The provision of professional expertise to the Authority

### Purpose of paper

1. To consider if the Authority will have sufficient professional expertise to make informed decisions and retain credibility with professional stakeholders.

### Recent developments

2. During summer 2009, the Authority undertook a review of its future composition and skills requirements in advance of the Department of Health's recruitment exercise for new Members. As part of this review, the Authority discussed the distinction between professional and lay Members for recruitment purposes.
3. While the Human Tissue Act (HT Act) does not define 'professional interest', it is clear that this relates to people who belong to a profession that falls within, or is affected by, the regulatory scope of the HT Act.
4. Lay Members bring skills, knowledge and professional experience from a range of backgrounds. This may include experience within organisations which represent those affected by practices within the regulated sectors. The HT Act requires that the Chair and at least half the membership must be lay.
5. At present, the Authority has four professional Members and eight lay Members (including the Chair). On 31 March 2010 four Authority Members will stand down as their term of appointment ends. This will leave the Authority with two professional Members, Mr Rigg (transplant surgeon) and Dr Reid (coroner) and six lay Members (including the Chair).
6. We will not know until the latest recruitment round is complete how many professional Members will sit on the Authority as of April 2010.

7. In September 2009 the Authority agreed a series of recommendations to put to the Department of Health about its future composition and skills requirements. Among these was the recommendation that:

*Strategic skills and experience will be of primary importance in the recruitment of new Members. Applications from candidates with these strategic skills who are also connected to, or have an understanding of, the regulated sectors should be particularly encouraged during the recruitment of Members. While the group recommended that there should not be a quota of professional Members, a concerted effort should be made in recruitment to ensure the continued presence of one or more respected senior professionals among the Authority's membership.*

### **How can the HTA obtain the professional expertise to make informed decisions?**

8. It is neither practicable nor desirable to have an Authority large enough to encompass all of the professional issues which may arise within the sectors regulated by the HTA. While part of good governance is to ensure that the views of stakeholders are properly accounted for in actions proposed by the executive, the Authority does not exist to represent the interests of licensed establishments or professional groups. This, in turn, implies that professional members are not appointed to represent the particular interests of the constituency from which they are drawn. The Authority's purpose is to set the strategic direction of the HTA and fulfil a governance role.
9. In order to meet this remit, the Authority should be assured that (a) sufficiently broad professional opinion has been taken into account in the papers on which it is asked to take a view, and (b) that it is sufficiently well informed to bring the right level of challenge to any recommendations on which it must take a decision.
10. The HTA has been recognised for its preparedness to seek the views of all stakeholders, particularly professionals, when developing policy. Examples include the formal consultations on the codes of practice and the fee structure; and ad hoc discussions with external professionals and workshops attended by professionals from a particular sector. Recent examples of engagement to develop policy include the communication flowchart for the post mortem sector and the preparation for conducting the planned audit of post mortem material. The diverse and varied mechanisms used by the HTA to seek external advice and opinion are listed in the Annex to this paper.

11. This external advice and the knowledge and experience within the executive combines to provide a formidable body of expertise that leads to good policy development and supports the Board in its decision making. Therefore, the issue is not so much one of insufficient knowledge or opinion, but of credibility. However, this is much less an issue now than at establishment in 2005. But even then, the membership did not include people drawn from all the sectors we regulate. The systems of engagement with externals that were developed immediately after establishment took shape precisely because we needed knowledge and expertise from the sectors and professions not represented on the Board. And even where we did (and do) have Board-level expertise we engaged, and continue to engage, others in the same professions to obtain a broader perspective. This continuing engagement leaves the HTA at minimal risk of losing credibility.

### **Appointment of new Members**

12. While the Authority has already made clear that the Board should consist of Members with good strategic skills, it does recognise the value of having professionals on the Board. The Authority took the view that the best way of achieving this would be to appoint candidates who have both strategic skills **and** wide medical or scientific experience: the person specification for new members has been drafted with this in mind.

13. The ways we continue to engage external professional advice and the likely appointment of further professional members should mean that the HTA's credibility will remain high. We propose to review the position in the unlikely event that no appointments of professionals are made in the next round of recruitment.

### **Conclusion**

14. Members should feel confident that the ways in which we continue to engage and use professional advice lead to good policy development and decision making. It is highly likely that professionals will be appointed in the forthcoming recruitment exercise. This will undoubtedly reinforce and supplement the knowledge base at Board and executive levels. If not, Members should note that we will review the position to ensure that the credibility of the HTA is not diminished.

**Annex - Existing sources of professional expertise**

<b>Group</b>	<b>Description</b>
Authority	As identified in the body of the paper the Authority continues to have professional Members.
HTA executive	HTA employees are drawn from a variety of medical, legal, regulatory, scientific and other professional backgrounds. This allows them to bring insight into the activities of the regulated sectors. In addition, many have developed good working relationships with individuals in the sectors that we regulate and other professionals, such as coroners, who are happy to provide assistance when invited to do so.
Ad hoc working groups and consultations	The HTA has convened ad hoc groups since it was established. These continue to be used regularly to help form policy, to provide practical advice on the implementation of an area of policy or to help resolve a problem or issue.
Links with stakeholder organisations	There is regular contact both through informal communication channels and formal meetings with a number of stakeholder organisations including the Home Office, the Association for Anatomical Pathology Technologists (AAPT), Royal College of Pathologists (RCPATH), Safety of Blood, Tissues and Organs, British Association for Tissue Banking, MHRA, HFEA, European Association of Tissue Banks, Bio Industry Association, Medical Research Council, Cancer Research, Encore and others.
Tissue and Cell Working Group - Permanent membership all executive staff but external bodies can be invited.	The Tissues and Cells (for Human Application) Working Group is established to provide both an internal forum for policy development but also as a forum for external bodies and experts to contribute to policy development.
Post Mortem Working Group - Permanent membership	The Post Mortem Sector Working Group has three core functions: to maintain strategic

<p>executive staff and Authority Members but external bodies can be invited.</p>	<p>oversight of the sector; to provide a forum for debate on sector-specific issues and inform implementation of resulting work streams and to report back to the Authority on key issues as necessary. The group meets quarterly and on an ad hoc basis, and includes representatives from RCPATH and the AAPT where necessary.</p>
<p>Transplant Working Group - Permanent membership executive staff, Authority Members and external specialists.</p>	<p>Transplant Working Group works on practical issues associated with living organ donation and develops practices which impact on clinical practice at a grass roots level.</p>
<p>SAEARS Group</p>	<p>The purpose of this meeting is to share information on noteworthy reported serious adverse events (SAEs) and serious adverse reactions (SARs) within the SAEARS team. The meetings are to ensure consistency in SAE/SAR assessment, follow-up and trend monitoring and identifying areas requiring policy development. Expertise from sources outside the HTA are sought where necessary.</p>
<p>Meetings with National Research Ethics Service (NRES)</p>	<p>There is a Memorandum of Understanding between HTA and NRES. The purpose of the biannual meetings is to discuss matters of mutual interest, sharing information and supporting each other by agreeing on consistent approaches.</p>
<p>EUSTITE (European Union Standards and Training in the Inspection of Tissue Establishments)</p>	<p>The EUSTITE project objective is to optimise and harmonise the standards and methods applied by Competent Authorities in the inspection and accreditation of tissue procurement and tissue establishments within the EU. A secondary objective is to propose common systems for definition, classification and reporting of adverse events and reactions that are consistent with similar systems in other parts of the world.</p>
<p>Development of Regulatory Methods</p>	<p>This is an ad hoc group that is set up by the sector according to demands.</p>

<p>Competent Authority Network</p>	<p>All Competent Authorities in 27 Member States, Council of Europe and European Commission. EC conferences and workshops provide the HTA with the opportunity to engage with representatives of other member states and horizon scan for forthcoming issues.</p>
<p>Conferences</p>	<p>Sector specific conferences provide the HTA with the opportunity to present the HTA's regulatory framework and also to contribute to debate on emerging issues, and to hear, first hand, the views of specialists employed in the regulated sectors.</p>
<p>Research</p>	<p>Research undertaken by the HTA to assess the impact of regulation. Can be sector specific, such as the Opinion Leader work to assess how regulation and requirements affect researchers working with human tissue.</p>
<p>Specialist Advisors, previously Specialist Assessors</p>	<p>SAs are made up of representatives from across all five licensed sectors that are trained in the HTA's regulatory approach. The original role of SAs was to provide expert advice and guidance to HTA inspectors during site-visit inspections. SAs are no longer widely used now that the HTA has developed its own expertise.</p>