

## Minutes of the forty seventh meeting of the Human Tissue Authority

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**Date** 25 January 2010

**Venue** The Westminster Conference Centre  
1 Victoria Street  
London  
SW1H 0ET

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### Present

#### Members

Baroness Diana Warwick (Chair)  
Professor Michael Banner  
Mrs Jodi Berg  
Mr Brian Coulter  
Professor Susan Dilly  
Mrs Rosie Glazebrook  
Mrs Pamela Goldberg  
Mrs Suzanne McCarthy  
Professor Gurch Randhawa  
Mr Keith Rigg  
Ms Catharine Seddon

#### In attendance

Mr Craig Muir (Chief Executive)  
Dr Alan Clamp (Director of Compliance and Enforcement)  
Dr Shaun Griffin (Director of Communications and Public Affairs / Interim Director of Policy)  
Mrs Sue Martin (Director of Resources)  
Mr Allan Marriott-Smith (Authority Secretary)  
  
Miss Ariel Armarego-Marriott (Resources Assistant)

#### Observers

Mr Edward Webb (Department of Health)  
Mr Patrick Irwin (Department of Health)

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Item	Title	Action
<b>Item 1</b>	<b>Welcome and apologies</b>	
	<ol style="list-style-type: none"> <li>1. Baroness Warwick welcomed Members and observers to the forty-seventh meeting of the Human Tissue Authority.</li> <li>2. Apologies had been received from Dr Andrew Reid.</li> </ol>	
<b>Item 2</b>	<b>Declarations of interest</b>	
	<ol style="list-style-type: none"> <li>3. There were no declarations of interest.</li> </ol>	
<b>Item 3</b>	<b>Minutes of 23 November 2010 [paper: HTA (01/11)]</b>	
	<ol style="list-style-type: none"> <li>4. The minutes of 23 November 2010 were adopted.</li> </ol>	
<b>Item 4</b>	<b>Matters arising</b>	
	<ol style="list-style-type: none"> <li>5. All actions from the previous meeting had been fulfilled or were in hand, with the exception of the paper on issues stemming from PACE and the Coroners Rules. This will be deferred to the March Authority meeting as Dr Reid could not be present at the January Meeting.</li> <li>6. There has still been no formal decision on which body will become the Competent Authority for the Organ Donation Directive. The Executive is undertaking business planning on the basis that the HTA will take the role.</li> <li>7. Following the oral report at the last meeting regarding the public position taken by the British Medical Association (BMA) on the ALB review, a meeting had taken place between HTA and BMA representatives. Shaun Griffin provided the Authority with an oral report on the outcome of the meeting which had been useful in reaching a shared understanding of the issues at stake, but did not change the BMA's position.</li> </ol>	
<b>Item 5</b>	<b>Chair's report</b>	
	<ol style="list-style-type: none"> <li>6. The Chair thanked Professor Banner for deputising as Chair during her absence in December.</li> <li>7. The Chair informed Members that she had held further discussions with Professor Lisa Jardine at the Human Fertilisation and Embryology Authority (HFEA) to discuss issues of common interest in relation to the Arm's Length Body (ALB) review. A meeting had also taken place with Mark Bale and Tedd Webb from the Department of Health, also to discuss the implications of the ALB review.</li> <li>8. The Chair had also attended a Peers meeting at the House</li> </ol>	

	<p>of Lords organised by Earl Howe to discuss issues raised by the ALB review for the HTA and the HFEA.</p> <p>9. The Chair invited Craig Muir to provide the Authority with a summary of the recommendations of the Academy of Medical Science's review of research regulation. In general the report was favourable about the role played by the HTA. The report had been mistaken on a number of issues concerning the HTA's approach to regulating certain materials, this position would be clarified. The report recommended a single research regulator; a conclusion which the Executive believes will not deliver the benefits envisaged by the Academy in relation to the regulation of human tissue.</p> <p>10. The Welsh Assembly Government has been consulting on the issue of presumed consent in organ donation for people who live and die in Wales. Members had been provided with a copy of the HTA's response to the consultation.</p> <p>11. The Chair asked Members to note that she had taken the decision to combine the public Authority meeting with the annual review event. As a result, the next public Authority meeting will take place in July.</p>	
<b>Item 6</b>	<b>Strategic Performance Review December 2010 [paper: HTA (02/11)]</b>	
	<p>14. Allan Marriott Smith introduced the paper which described the HTA's performance against Key Performance Indicators (KPIs). He drew particular attention to the activity undertaken by the Staff Survey Working Group (SSWG) to identify the issues which contribute to staff turnover and the actions which are being taken as a result.</p> <p>15. Two issues were discussed.</p> <p>i. Five posts are currently being actively recruited. Following the arrival of the new Director of Compliance and Enforcement, the Executive is reviewing the organisational structure. As part of this review, a decision will be taken on how many of the other currently vacant posts will need to be filled. Craig Muir assured Members that, while a number of operational pressure points exist, current staffing levels are sufficient to undertake business critical activity. This has been possible by achieving efficiencies in business operations.</p> <p>ii. Members expressed concern that compliance information was not being received from establishments within required timescales. This will be a topic for discussion at the next Regulation Members' Group meeting.</p>	

	<b>Action: Authority Members to be copied in on the staff newsletter for information.</b>	<b>SG</b>
<b>Item 7</b>	<b>Financial Report December 2010 [paper: HTA (03/11)]</b>	
	<p>16. Sue Martin introduced the paper, which described the financial position as at the end of December 2010.</p> <p>17. Authority Members sought clarification on two issues.</p> <p>i. The position described in paragraph 17 of the paper, relating to the reduction in the number of licences, is thought to be associated with establishments rationalising the number of licences they hold.</p> <p>ii. Members asked for clarification on the variance shown in Annex B relating to income from devolved administrations,</p> <p>18. The paper was accepted for information.</p> <p><b>Action: Members to be provided with an explanation for the variance shown in Annex B relating to income from devolved administrations,</b></p>	<b>SM</b>
<b>Item 8</b>	<b>Criteria for judging ALB review options [paper: HTA (03/11)]</b>	
	<p>19. Craig Muir introduced the paper which had been produced at the request of the Authority at its November meeting and set out a range of criteria against which options for the transfer of the HTA's functions can be judged. In making an assessment of the various options, the Executive had concluded that the criteria would best be met by keeping the HTA's functions together as a single entity.</p> <p>20. In discussion, a number of themes emerged:</p> <p>i. Keeping the HTA's functions together in a single entity garnered unanimous support from the Authority as the transfer option that best met the criteria.</p> <p>ii. Several Members expressed reservations about the CQC being the appropriate body to receive the HTA's functions. Two specific concerns were put forward: the different styles of regulation which are adopted by the HTA and the CQC; and a weakening of accountability in the regulation of human tissue as a result of both the scale of the HTA relative to the CQC and the relative priorities within CQC as its remit expands.</p> <p>iii. Concerns were also voiced on the issues associated with sharing services with the CQC. Costs, risks and accountability issues will all require careful consideration.</p> <p>iv. Members were keen to know more about the views of patient groups on the transfer options.</p> <p>21. Members agree to adopt the criteria and endorsed the single</p>	

	<p>entity approach as being the organisational model that will best meet the criteria.</p> <p><b>Action: In meetings with Ministers and the Department of Health the “all functions” approach will be vigorously pursued.</b></p> <p><b>Action: An update on the approach to shared services will be brought to a future Authority meeting.</b></p>	<b>CM</b>
<b>Item 9</b>	<b>Findings from the audit of post-mortem establishments [paper: HTA (05/11)]</b>	
	<p>22. Alan Clamp introduced the paper which described the progress made with the audit of post-mortem establishments which had been undertaken following the issue of General Directions in April 2010. Data quality issues and the need for follow up with a number of establishments had delayed progress with producing the report.</p> <p>23. A number of points were made during the discussion.</p> <p>i. The Authority will need to see more detailed results before the benefits of undertaking the audit can be properly understood.</p> <p>ii. The Association of Chief Police Officers (ACPO) has also commissioned an audit of retained material from the same establishments. Members noted the risks associated with the HTA and ACPO audits reaching significantly different conclusions. Communication of the findings of both audits will be coordinated by a Gold Group on which the HTA is represented.</p> <p>iii. If unresolved retention issues remain following data quality checks, the relevant establishments must be prioritised for further investigation and swift and appropriate regulatory action if this proves necessary.</p> <p>iv. Concerns were expressed that two establishments have failed to supply audit information.</p> <p>v. Strategic focus on the standards in the post mortem sector must be maintained during any transition resulting from the ALB review.</p> <p><b>Action: The Executive will provide Members with an update on the key findings from the audit by the end of February 2010.</b></p> <p><b>Action: The full report from the audit will be presented at the March Authority meeting.</b></p>	<p><b>AC</b></p> <p><b>AC</b></p>
<b>Item 10</b>	<b>Significant regulatory activity report – 1 October to 31 December 2010 [paper: HTA (06/11)]</b>	
	24. Alan Clamp introduced the paper, which is a regular item	

	<p>which sets out the significant regulatory action undertaken by the HTA in the quarter ending December 2010.</p> <p>25. The Authority considered the content of the report and made a number of comments:</p> <ul style="list-style-type: none"> <li>i. Members expressed concern that 24 hour reporting of Serious Adverse Events and Reactions (SAEARs) was significantly below target. This poses a potential risk to the HTA reputation, if a serious adverse event is reported by the media before the HTA has been informed.</li> <li>ii. There are likely to be varying degrees of the severity of SAEARs and Serious Untoward Incidents (SUIs). Those with potential to affect patient safety being the most serious. Further explanation is required on the rationale for 24 reporting in all cases.</li> </ul> <p><b>Action: The Executive will look into the basis for reporting of all SAEARS within 24 hours and will consider ways to ensure establishments meet this standard.</b></p> <p><b>Action: The Executive will convene a meeting of the Regulation Members' Group to work through the approach to reporting significant regulatory action. This will take place before the next report comes to the May Authority meeting.</b></p>	<p>AC</p> <p>AC</p>
<b>Item 11</b>	<b>Summary of post-inspection feedback from 2010 [HTA (07/11)]</b>	
	<p>26. Alan Clamp introduced the paper, which presented the feedback from establishments on the inspection process.</p> <p>27. Members welcomed the positive messages set out in the report. They also stressed that establishments should be strongly encouraged to complete feedback forms to ensure that the HTA can improve its regulatory processes.</p> <p><b>Action: Future reports should, if possible, include an indication of the number of responses which were received anonymously.</b></p>	<p>AC</p>
<b>Item 12</b>	<b>Domino paired living organ donation [HTA (08/11)]</b>	
	<p>28. Shaun Griffin introduced the paper which set out the proposals for the approval of domino paired living organ donation.</p> <p>29. Members discussed a number of issues raised by the paper and approved the recommendation that these cases be referred to a panel for a decision.</p> <p><b>Action: HTA will develop a policy and procedure for organs that cannot be transplanted into the intended recipient.</b></p>	<p>SG</p>

<b>Item 13</b>	<b>HTA policy on composite tissue (09/11)]</b>	
	30. Shaun Griffin introduced the paper. 31. The Authority accepted the paper for information and expressed the view that consistency across the EU in definitions should be an important consideration in the next steps.	
<b>Item 14</b>	<b>Operation of the living organ donation system (10/11)]</b>	
	32. Shaun Griffin introduced the paper, the first in a new style of quarterly reporting to the Authority. 33. The Authority accepted the paper for information.	
<b>Item 15</b>	<b>Update in non-genetically or emotionally related directed donation (Oral report)]</b>	
	34. Shaun Griffin provided an oral report on the project which has been established to look into the assessment of directed organ donation in cases where the donor and recipient are neither emotionally nor genetically related. 35. An independent assessment working group has been established to oversee this work. The group will be chaired by Craig Muir and Catharine Seddon, Suzanne McCarthy and Keith Rigg would be invited to provide Member input. The group will meet next after the Authority meeting in March.	
<b>Item 16</b>	<b>Any other business</b>	
	<b>Action: The Executive will provide a full list of the Authority's committees and groups and their membership to Members.</b>	<b>AMS</b>

The meeting closed at 1.00 pm