

Minutes of the fifty-second meeting of the Human Tissue Authority

Date 22 November 2011

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

Present

Members

Baroness Diana Warwick (Chair)
Professor Michael Banner
Mrs Jodi Berg
Mrs Rosie Glazebrook
Mrs Pamela Goldberg
Mrs Suzanne McCarthy
Professor Gurch Randhawa
Dr Andrew Reid
Mr Keith Rigg
Ms Catharine Seddon

In attendance

Dr Alan Clamp (Chief Executive)
Mrs Sarah Bedwell (Director of Regulation)
Dr Christopher Birkett (Head of Regulation)
Mrs Sue Gallone (Director of Resources)
Dr Shaun Griffin (Director of Communications and Public Affairs)
Mr Allan Marriott-Smith (Director of Strategy and Quality)
Mrs Victoria Marshment (Authority Secretary)
Ms Imogen Swann (Head of Regulation)

Observers

Ms Morounke Akingbola (Head of Finance)
Dr Hazel Lofty (Regulation Manager)
Ms Audrey Raymond (Executive Assistant)
Mr Mark Bale (Department of Health)
Mr Ted Webb (Department of Health)

Item	Title	Action
Item 1	Welcome and apologies	
	<ol style="list-style-type: none"> 1. Baroness Warwick welcomed Members and observers to the fifty-second meeting of the Human Tissue Authority. 2. Apologies had been received from Mr Brain Coulter and Professor Susan Dilly. 	
Item 2	Declarations of interest	
	<ol style="list-style-type: none"> 3. Mr Keith Rigg declared an interest in item eight as the transplant unit in which he works as a surgeon will be subject to licensing and licence fees in August 2012. 	
Item 3	Minutes of 27 September 2011 [paper: HTA (52/11)]	
	<ol style="list-style-type: none"> 4. The minutes of 27 September 2011 were adopted. 	
Item 4	Matters arising	
	<ol style="list-style-type: none"> 5. All actions from the previous meeting had been completed or were in hand. 6. Contact had been made with the Health Select Committee, and although Members of the Committee are too busy to meet with us at the present time they would appreciate a briefing note, which will be prepared by the Communications team. 7. The HTA's stakeholder lists of those organisations and individuals to be sent the Arm's Length Bodies (ALB) consultation document is near completion. It will be sent to the Department of Health in coming weeks. 8. An update on the Competent Authorities meeting for the EU Organ Donation Directive (ODD) is covered at item six. 9. Following a discussion at the HTA Management Group (HTAMG) in early November, the decision was taken not to undertake a review of all the HTA's Codes of Practice at this stage as there was neither the demand nor resource to do so. 10. A paper on the proposed response to the Welsh Government's White Paper on an opt-out system for organ donation is covered at item ten. 11. As the application to establish a 'body farm' (taphonomy site) in the UK has been withdrawn there are no longer plans to bring a paper on this to the January meeting. <p>Action: To prepare a briefing note on the HTA for the Health Select Committee.</p>	SGr

Item 5	Chair's report	
	<p>12. Diana, Alan and Shaun had met Earl Howe, Parliamentary Under Secretary of State, in mid-October to provide an update on the work of the HTA and to discuss the ALB review. The meeting was both amicable and productive and it was clear that Earl Howe have received positive messages about the HTA from our stakeholders. Earl Howe was aware of the work of the HTA and the steps we are taking towards greater collaboration with other regulatory bodies, and thanks were passed on to Department of Health colleagues for ensuring the flow of information.</p> <p>13. A meeting was also held with David Harper, Director General for Health Improvement and Protection at the Department of Health, which was very positive.</p> <p>14. Diana, Alan and Shaun met with senior representatives of the British Medical Association (BMA), who had received positive feedback about the HTA from their membership groups, and acknowledged our efforts to work more collaboratively.</p> <p>15. Diana had attended a Royal College of Pathologists (RCPATH) dinner and had a constructive conversation with the incoming President, Dr Archie Prentice, and has arranged to meet him once he takes office. Diana informed Members that Professor Mike Wells had fed back through the professional engagement project that the RCPATH's relationship with the HTA has improved. However, their remaining concern relates to our requirements on blocks and slides.</p> <p>16. Ted Webb added that any feedback which can be provided to the Department of Health on stakeholder's perceptions of the HTA would be valuable.</p> <p>17. The results of the 2011 staff survey had been circulated to staff and discussed at the all staff meeting held on 21 November. The results were broadly positive and the HTA scored well against other comparable organisations. Two key areas for improvement were identified as learning and development and pay and conditions. It was felt that this was the right time to raise the problem of potential staff turnover with the Department of Health. A career investment scheme has been developed and this is an item which could be discussed at a meeting of the Remuneration Committee.</p> <p>18. It was noted that the results of the survey on pay and</p>	

	<p>conditions placed the HTA lower than the average for public sector bodies. Diana and Alan are attending meetings with their counterparts at other ALBs in early December and will raise this matter to better understand how others are tackling such issues.</p> <p>19. The inspection feedback received for quarters one and two was very positive with 99% of establishments rating the process as either excellent or good, and two-thirds of that number rating it as excellent. The Authority paid tribute to our Regulation Managers and their commitment to delivering work of the highest quality.</p> <p>20. Diana was copied into a letter from Dame Jo Williams the Chair of the Care Quality Commission (CQC) to Simon Burns MP, Minister of State for Health, which outlined the instruction the CQC Board had given to their Executive to conduct a root and branch investigation on the benefits and disadvantages of the CQC taking on the HTA's and Human Fertilization and Embryology Authority's (HFEA's) functions. This was in light of a recent report from the Health Select Committee which had expressed concern at the range of functions and activities the CQC was being charged with. The findings of this investigation would be submitted as evidence to the Health Select Committee.</p> <p>Action: To update the Department of Health on feedback received from stakeholders over recent months.</p> <p>Action: To schedule a meeting of the Remuneration Committee in early 2012.</p>	<p>SGr</p> <p>SGa</p>
Item 6	Update on the implementation of the Organ Donation Directive [paper: HTA (53/11)]	
	<p>21. Imogen Swann introduced the paper and gave an overview of the progress made so far on the project to implement the EU Organ Donation Directive (ODD).</p> <p>22. It was confirmed that the earliest the Statutory Instrument (which will introduce the Directive into UK legislation) will become law is May 2012; therefore the HTA was proceeding with some activities at risk. This is to ensure that a licensing system is in place for August 2012. The option of issuing deemed licences has been considered and will be reserved as a contingency plan.</p> <p>23. The first meeting of the Competent Authorities for this Directive was held in September. At this stage there was little substantive information to be shared and the discussion focussed on the Action Plan which accompanies the Directive. Members asked whether there was a risk that</p>	

	<p>in order to ensure timely implementation, the robustness of the mechanisms and systems would potentially be compromised. It was confirmed that although the timescales were challenging, significant effort had been placed on ensuring the quality of the processes.</p> <p>24. It was noted that the HTA consultation document had not been discussed by the Authority prior to publication. It was decided that a review of the process for publication should be undertaken and a copy of the consultation circulated to Members.</p> <p>25. It was requested that a list of indicative action dates be sent to transplant units so they are aware of the work which will need to be undertaken during 2012.</p> <p>26. The work with NHS Blood and Transplant (NHSBT) on assisted functions has now reached the stage of drafting contracts and the respective legal teams are aiming to have these in place by the end of the business year.</p> <p>27. The Authority noted the content of the paper.</p> <p>Action: To feedback to the January meeting on the process for issuing a document for consultation, and the process followed for the ODD consultation.</p> <p>Action: To send a communication out to transplant units with indicative action dates during 2012.</p>	<p>SB</p> <p>SB</p>
<p>Item 7</p>	<p>Strategic plan 2012 to 2015 and the strategic risk register – sign off [paper: HTA (54/11)]</p>	
	<p>28. Allan Marriott Smith presented the paper which included at Annex A the revised strategic plan. This reflected the comments made by Members at the awayday in September. This document will set the direction for the business planning round which has recently started and which will include an all staff awayday on 5 December.</p> <p>29. Sue Gallone provided information on the changes which had been made to the strategic risk register, included at Annex B, and how these reflected the discussions at the awayday. This had been reviewed by the Audit Committee at their meeting on 4 November.</p> <p>30. Members said that both documents were a fair reflection of the discussions, and felt the nuances had been captured well.</p> <p>31. The Authority signed off both the strategic plan and the strategic risk register.</p>	

Item 8	Fees proposals for 2012/13 [paper: HTA (55/11)]	
	<p>32. Sue Gallone introduced the paper and provided Members with further information on the proposed fees for 2012/13.</p> <p>33. Following discussions at the awayday, and taking into consideration objective information as well as staff estimates of time spent, it has been calculated that we should seek to recover £3.7m in fee income during 2012/13. This includes some contingency.</p> <p>34. There are two changes to be implemented in 2012/13. Firstly, the transplantation sector will become licensed in August 2012 and fees will be introduced in this sector. Secondly, the amalgamation of many post mortem services means that there are an increasing number of satellite sites in this sector and more resource is required to licence them. It is intended that there will be two types of licence for post mortem satellites, one for standard sites and one for sites that only store blocks and slides.</p> <p>35. The fees for the transplantation sector rely on a number of assumptions, one of which is that some units will decide on multiple licences to ensure the employment of specialist Designated Individuals.</p> <p>36. Negotiations are underway with NHSBT regarding the cost of the assisted functions they will perform on behalf of the HTA under the ODD.</p> <p>37. Members questioned the relatively small budget that has been allocated as contingency. It was explained that for an organisation such as the HTA with largely fixed costs, the amount allocated is within the normal range.</p> <p>38. It was confirmed that while the HTA does not have to seek approval of fees from the Treasury, we will be sharing our plans with them once finalised.</p> <p>39. The Authority approved the recommendations in the paper.</p>	
Item 9	Framework for living organ donation assessment - proposal [paper: HTA (56/11)]	
	<p>40. Allan Marriott-Smith informed members that this paper had been drafted following the IAWG meeting held on 25 October. A second Annex was tabled which detailed a proposed framework for the assessment of living organ donation cases.</p> <p>41. The framework reflects the draft legal advice received from counsel on this issue and the discussions at the British Transplantation Society's Living Donation Forum held on 15 November.</p>	

<p>42. Members discussed the allocation schematic provided at Annex A and agreed this on the proviso that amendments were made to the terminology used in the final section of Table A.</p> <p>43. Agreement was reached that the Executive should develop a model signed statement which every living donor and recipient will be required to complete prior to the Independent Assessment interview. Further advice should be sought to establish whether such a statement would have standing under section nine of Criminal Justice Act 1967 to allow it to be used as evidence in criminal proceedings if necessary.</p> <p>44. It was agreed that a clearly specified psychiatric/psychological report would be one of the further investigation options for complex cases, as would a directed IA interview. It was noted that there may be benefit in training a small group of Independent Assessors to conduct these interviews.</p> <p>45. The question of financial investigations was more complex as the draft legal advice suggested this would only be a possibility where we are able to show a direct link between the information we would be requesting and the requirements laid out in the Transplant Regulations 2006. The Authority agreed not to pursue financial investigations as an enquiry for all complex cases.</p> <p>46. Members were satisfied that if, following panel consideration of a case, they still had residual concerns that the requirements of the Regulations had not been met they would request legal advice on the possible next steps.</p> <p>47. It was agreed that there would need to be further panel training provided to ensure all Members were fully aware of the new assessment framework and the options available in complex cases.</p> <p>48. The Authority approved the recommendations and next steps in the paper.</p> <p>Action: To circulate the final legal advice from counsel on an assessment framework for living organ donations.</p> <p>Action: To develop training for panel members on the assessment of complex cases.</p>	<p>AMS</p> <p>AMS</p>
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Item 10	Update on the introduction of an opt-out system in Wales [paper: HTA (57/11)]	
	<p>49. Allan Marriott Smith introduced the paper which outlined the HTA's proposal to respond to the White Paper issued by the Welsh Government on their plans to introduce an opt-out system for organ donation.</p> <p>50. It was agreed that the HTA should respond to the consultation, in particular drawing attention to the impact of this change on our role as regulator and the amendments which will need to be made to a range of statutory documentation, including the Human Tissue Act 2004 and a number of our Codes of Practice.</p> <p>51. Members noted that, as individuals will still have the opportunity to opt-in by signing the Organ Donor Register (ODR), and families will still be involved in the decision making, the proposal had similarities with a system of mandated choice (which involves an individual being compelled to make a choice, whether it be yes or no).</p> <p>52. It was confirmed that the Department of Health would be responding to the White Paper and would liaise with the HTA on this.</p> <p>53. The Authority agreed the recommendations in the paper.</p> <p>Action: For a draft of the response to the Welsh White Paper on the introduction of an opt-out system to be discussed at the Policy and Regulatory Activity Group meeting on 10 January 2012, with the final version being agreed at the 24 January Authority meeting.</p>	AMS
Item 11	Removal for a scheduled purpose – licensing recommendation [paper: HTA (58/11)]	
	<p>54. Chris Birkett introduced the paper which detailed plans to introduce a licence for the removal of tissue from the deceased for a scheduled purpose.</p> <p>55. The transplant community has expressed the view that our licensing regime lacks flexibility: there is a requirement that tissue removed from the deceased for a scheduled purpose takes place on licensed premises, however this requirement does not exist for the purpose of transplantation.</p> <p>56. We have sought to address this through the extension of post mortem licences but this is not always appropriate or effective.</p> <p>57. The HTA intends to introduce a new licence type which will be fit for purpose and future proofed. In addition to</p>	

	<p>addressing issues raised by the transplant community, the new licence can also be used for health monitoring purposes (for example in a flu pandemic) and for post mortem examinations which take place outside mortuaries (for example in imaging suites).</p> <p>58. Members requested that the new licence type also took into account the removal of tissue from children who die in the accident and emergency department.</p> <p>59. The new licence will be introduced by the end of Q2 2012/13.</p> <p>60. The Authority noted the content of the paper.</p>	
Item 12	Regulatory Activity Report – July-September 2011 [paper: HTA (59/11)]	
	<p>61. Alan Clamp told Members that a draft of this paper had been discussed at, and endorsed by, the Policy and Regulatory Activity Group meeting on 2 November and the minutes of this meeting had been circulated.</p> <p>62. The Authority noted the content of the paper.</p>	
Item 13	ALB Review and shared services [paper: HTA (60/11)]	
	<p>63. Alan Clamp introduced the paper and confirmed that a debate on the Health Research Agency was scheduled in the House of Lords in coming weeks.</p> <p>64. There had been a more consultative approach taken on the shared services agenda and, as a result, more information was being shared between organisations.</p> <p>65. The draft ALB consultation document would be forwarded to the SMT for comment soon.</p> <p>66. The Authority noted the content of the paper.</p>	
Item 14	Report from the Audit Committee November 2011 [paper: HTA (61/11)]	
	<p>67. Michael Banner introduced the report, which included the minutes of the Audit Committee meeting of 4 November.</p> <p>68. The Authority noted the content of the report.</p>	
Item 15	Financial report October 2011 [paper: HTA (62/11)]	
	<p>69. Sue Gallone introduced the report which detailed the financial position to end of September 2011.</p> <p>70. Sue confirmed that training and development opportunities were being considered as areas where part of the under spend for 2011/12 could be usefully allocated, particularly as there had been relatively little training and development activity in the first half of 2011/12.</p>	

	71. The position with debtors has improved further since the report was produced and legal letters have been sent to the remaining debtors. 72. The Authority noted the content of the paper.	
Item 16	Strategic performance review October 2011 [paper: HTA (63/11)]	
	73. Allan Marriott Smith introduced the report which gave Members an update of progress against key performance Indicators (KPIs). 74. The Authority noted the content of the report.	
Item 17	Any other business	
	75. There was no further business and the Chair wished Members a happy Christmas.	

The meeting closed at 1.15 pm