Minutes of the sixtieth meeting of the Human Tissue Authority

Date  18 March 2013
Venue  Westminster Conference Centre
       1 Victoria Street
       London
       SW1H 0ET

Present

Members
Baroness Diana Warwick (Chair)
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
Mrs Sarah Bedwell (Director of Regulation)
Dr Alan Clamp (Chief Executive)
Mrs Sue Gallone (Director of Resources)
Dr Shaun Griffin (Director of Communications and Public Affairs)
Ms Elvira Manjaji (Regulation Manager)
Mr Allan Marriott-Smith (Director of Strategy and Quality)
Mrs Victoria Marshment (Authority Secretary)

Observers

Mr Patrick Irwin (Department of Health)
Mr Ted Webb (Department of Health)
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<tr>
<th>Item</th>
<th>Title</th>
<th>Action</th>
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| Item 1 | Welcome and apologies | 1. Baroness Warwick welcomed Members and observers to the sixtieth meeting of the Human Tissue Authority (HTA).  
2. Apologies had been received from Professor Michael Banner. |
| Item 2 | Declarations of interest | 3. There were no declarations of interest. |
| Item 3 | Minutes of 22 January 2013 [paper: HTA (10/13)] | 4. The minutes of 22 January were adopted with one amendment.  
5. The action under item 9 on the complaints report should read “For the complaints policy to be amended to reflect that a report would be considered by the Authority every six months.”  
**Action:** For the minutes of 22 January 2013 meeting to be amended to state that the complaints report would be considered every six months. |
| Item 4 | Matters arising | 6. A note addressing matters arising was circulated to Members on 12 March.  
7. A note had been circulated to all staff on 5 March thanking them for their hard work on the successful implementation of the EU Organ Donation Directive.  
8. The next complaints report would be an agenda item at the September Authority meeting.  
9. In future the complaints report would be an agenda item at the March and September Authority meetings.  
10. The HTA’s standing orders were updated to reflect the decision-making framework as presented at the January Authority meeting. The updated standing orders had been sent to the Department of Health (DH) and published on the HTA’s website.  
11. The strategic risk register had been updated to remove references to the EU Organ Donation Directive and the Living Organ Donation Framework. |
| Item 5 | Chair’s report | 12. There had been a series of meetings with Justin |
McCracken regarding the review of the HTA’s and Human Fertilisation and Embryology Authority’s (HFEA) respective functions.

13. Headline feedback from the stakeholder interviews which had been conducted as part of the review had been shared.

14. The HTA ran an organisation-wide Leadership and Business Planning Day on 11 February. The morning session was led by Alan Clamp and focused on the ways in which all HTA staff could improve their leadership skills. Diana Warwick attended the afternoon session which reviewed the developing business plans for 2013/14 and at which staff of all grades had the opportunity to present.

15. The HTA ran an extremely successful conference as part of the SOHO V&S project (Substances of Human Origin, Vigilance and Surveillance) between 18 to 20 February. It was noted that the case studies presented by other countries highlighted the potential consequences when due vigilance was not routine and consistent.

16. There had not yet been any formal notification from DH on the reappointment of the four Members whose terms of appointment finish at the end of March. DH had informed the HTA that a decision on the appointment of an additional professional Member would not be taken until Justin McCracken’s review was completed.

17. Information on the meetings attended by the Chair, Chief Executive and members of the Senior Management Team (SMT) was included in the paper supporting item 14 on the agenda.

**Item 6 Independent review of HTA and HFEA [paper: HTA(11/13)]**

18. Alan Clamp introduced the paper which gave an overview of the review of the HTA and HFEA which DH had commissioned Justin McCracken to undertake.

19. The Authority had not met since the announcement on 25 January that the HTA and HFEA would not be merged into the Care Quality Commission (CQC) and that an independent review would be undertaken.

20. The independent review’s terms of reference cover streamlining the way the HTA and HFEA undertake their functions, the options for a reduction in the burden of regulation, and the scope for a merger of the two bodies.
21. The report is scheduled to be published in late April. It is expected that the draft recommendations would be shared with the HTA in mid-April.

22. Justin McCracken had provided a note on the themes which had emerged from his interviews with stakeholders. These were:
   a. Public confidence in the sensitive areas regulated by the HTA is now high. Specialist expertise and focus in the regulator are key elements in maintaining this.
   b. The burden of regulation is the biggest issue for those stakeholders interviewed so far.
   c. Recognition that the HTA takes a positive approach to listening to stakeholders’ views, and to change.
   d. The HTA’s agreement with the Human Research Authority (HRA) is seen as good practice.
   e. Progress in developing closer cooperation with other regulators is recognised, and more could be done in this regard.
   f. Concerns were expressed from the bioscience sector about the complexity created by the two separate regimes of the HTA and the Medicines and Healthcare products Regulatory Agency (MHRA). Joint inspections were welcomed as step in the right direction, but a seamless regulatory pathway is needed to facilitate the development of cell-based therapies.
   g. Eliminating overlaps with Clinical Pathology Accreditation (CPA) inspections is seen as important.
   h. Evidence that understanding among stakeholders of the HTA’s approach to regulation and the way this is developing is uneven, and a more structured approach to engagement on this issue might be beneficial.
   i. Support was articulated for further reductions in cost.
   j. HTA fees should be more transparent and predictable and consideration should be given to establishing a standing industry liaison group.
   k. Mixed views were expressed about the concept of merger.

23. The review would consider a range of potential merger options to realise further efficiencies, the uniting theme of these being the co-location of the two bodies.

24. Members noted that The Mid Staffordshire NHS Foundation Trust Public Enquiry Report recommended
that there should not be any unnecessary organisational change within the health sector. Effective regulation and patient confidence and protection should be a priority.

25. The Authority recalled that in 2006/7 Parliament had considered the merits of merging the HTA and HFEA to form the Regulatory Authority for Tissues and Embryos (RATE). At that time the view had been that this would not lead to effective regulation.

26. There was discussion as to the level of actual savings which could be made, as the HTA’s non-licence fee income is relatively low at £770k per annum. The Authority was advised that the potential savings identified by the review were indicative at this stage, and would require further analysis.

27. Members expressed concern at the continued uncertainty for the staff of the HTA and the potential impact on attrition and retention figures, which had been much improved over the previous year.

28. It was noted that there may be greater efficiencies to be gained by collaborations with bodies other than, or in addition to, the HFEA and the review’s terms of reference were somewhat limiting.

29. Members shared their experiences of mergers in both the public and private sectors and noted that, more often than not, the envisaged savings had not been realised.

30. It was stressed that while a focus on reducing regulatory burden was important, the protection of patients and the public should be the priority.

31. Colleagues from DH reinforced the point that the review was independent of Government.

32. Members stated that it was imperative for the HTA to maintain its commitment to making further efficiencies and increasing collaboration.

33. Members noted that under any proposal there must be certainty that the HTA’s core functions continue to be delivered effectively and with public confidence. Any merger must lead to better, or at the very least equivalent, standards of regulation.

34. It was agreed that the Chief Executive would summarise the points made by Members to form the basis of an HTA submission to the review, which would be approved by the Chair on behalf of the Authority.

35. The Authority noted the content of the paper.

Action: For the Chief Executive to draft an HTA
### Item 7  
**HTA Code of Practice on the donation of organs for transplantation after death in Wales [paper: HTA(12/13)]**

36. Allan Marriott-Smith introduced the paper and informed Members that the Minister for Health and Social Care at the Welsh Government had committed to a Code of Practice being available for the end of May when she gave evidence to the Health and Social Care Committee on 10 February.

37. SMT and the Chair made the decision that the benefits of the HTA committing (on a best endeavours basis) to providing a draft Code of Practice by this date outweighed the risks.

38. The HTA had made clear to the Welsh Government that the Code of Practice would be an HTA document, and, where consensus cannot be reached by mid-May, minority views would be represented by annotations to the main body of the text.

39. Members would have opportunity to review the working document during the period 11-25 April, and the near final draft at the meeting on 28 May.

40. External legal input would be sought, as well as that of an ethicist.

41. The Code of Practice would be subject to public consultation later in the calendar year.

42. Members noted that the Health Minister of the Northern Ireland Assembly had committed to consulting on the introduction of an opt-out system for deceased organ donation. This should be considered when drafting the Code of Practice to ensure that, as far as possible, the high level regulatory principles in regard to an opt-out system are clearly defined to support the policy development elsewhere in the UK.

43. The Authority noted the content of the paper.

### Item 8  
**Paired kidney exchange with the Republic of Ireland [paper: HTA(13/13)]**

44. Allan Marriott-Smith introduced the paper which provided an overview of arrangements currently in-place for donor and recipient pairs from the Republic of Ireland to enter the UK living kidney sharing schemes.

45. At present a donor and recipient pair are admitted to the
Walsgrave hospital in Coventry where the surgeries take place. As such, the independent assessment required by Regulations under the Human Tissue Act 2004 is carried out by an HTA Independent Assessor (IA) in Coventry.

46. The HTA received an enquiry about the possibility of the surgeries taking place at the Beaumont Unit in Dublin, with the kidneys being transported.

47. Members considered the likelihood of other European countries wishing to join the UK’s kidney sharing schemes and the additional burden this would place on the IA system.

48. It was clarified that both the HTA and NHS Blood and Transplant (NHSBT) considered this to be a pilot, and at the present time there was no interest from other countries.

49. The number of donor and recipient pairs from the Republic of Ireland entering the scheme in future would be low. The cost implication for the HTA would be related to identifying and training an IA to be based at the Beaumont Centre. It was envisaged that this would be done via the regular bi-annual training.

50. The Authority noted the content of the paper and agreed that work on the pilot should be progressed.

**Action:** That work be undertaken to establish and implement the HTA’s requirements to facilitate local surgeries for donors and recipients from the Republic of Ireland entered into the UK kidney sharing schemes.

### Item 9

**Report of the Audit Committee meeting 7 February 2013**

[paper: HTA(14/13)]

51. Catharine Seddon introduced the item and gave an update on the Audit Committee meeting of 7 February.

52. It had been agreed with the internal auditors that their focus for the rest of the year would be on efficiencies, rather than transition.

53. There would be a National Audit Office (NAO) facilitated workshop on self-assessment of performance for members of the Audit Committee.

54. It had been agreed that the level of reserves would be reviewed by the Committee in six months’ time.

55. No changes had been made to the Audit Committee Handbook.

56. It was noted by the Committee that SMT’s commitment to a culture of openness had been commended by the NAO. This allowed the Committee to have confidence in
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<th>Item 10</th>
<th>Authority scrutiny of risk register [paper: HTA(15/13)]</th>
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<td>57. The Authority noted the content of the paper and approved the Audit Committee Handbook.</td>
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| 58. Sue Gallone introduced the paper and gave an update on the strategic risk register.  
59. During SMT’s most recent review of the register it was agreed that the risk relating to relationship management had not yet changed, but SMT was live to the potential impact of the independent review of the HTA and HFEA as well as the production of a Code of Practice on deemed consent in Wales.  
60. Members asked that a note be added to the strategic risk register key to differentiate between amber and yellow risk ratings.  
61. The Authority noted the content of the paper.  
**Action:** For a note be added to the key of the strategic risk register to differentiate between amber and yellow risk ratings. |
| Item 11 | Strategic plan 2013 to 2016 [paper: HTA(16/13)] |
| 62. Allan Marriott-Smith introduced the paper and the draft strategic plan 2013-16 document.  
63. The plan would be published on the HTA’s website on 2 April, subject to final input from Members.  
64. It was agreed that high-level information should be included on the committee structure of the HTA. This would provide further assurance on the mechanisms in place to meet strategic aim four on governance and management.  
65. The Authority noted the content of the report and approved publication with the addition of committee information.  
**Action:** For high-level information on the committees of the HTA to be included in the final strategic plan 2013-16. |
| Item 12 | Regulatory Activity Report Q3 [paper: HTA(17/13)] |
| 66. Sarah Bedwell introduced the report which had been discussed at the Policy and Regulatory Activity Group meeting of 12 March.  
67. There had been a successful mediation process |
undertaken with a licensed establishment which in the first instance had failed to comply with Directions issued on the processing and storage of stem cells.

68. A review of the mediation process would be undertaken to establish whether this could become a standard step when escalation of non-compliance is required.

69. It was confirmed that the HTA had not needed to employ external mediators, and as such the costs incurred were low.

70. A paper on Serious Untoward Incidents (SUIs) and Serious Adverse Events and Reactions (SAEARs) would be brought to the May Authority meeting to consider in more detail the rise in the number of SUIs and the reasons for this.

71. It was noted that when unreported SUIs are identified by a Regulation Manager on inspection, the establishment is now required to report these, which may in part have contributed to the increase.

72. It was agreed that the paper on SUIs and SAEAR would include a trend analysis, the results of which would be communicated to the relevant sectors.

73. The Authority noted the content of the report.

**Action:** For a paper on SUIs and SAEARs to be brought to the May Authority meeting.

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<th>Item</th>
<th>Living Donation Activity Report Q3 [paper: HTA(18/13)]</th>
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<td>74.</td>
<td>Allan Marriott-Smith introduced the report which had been discussed at the Policy and Regulatory Activity Group meeting on 12 March.</td>
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<td>75.</td>
<td>There had been an increase in the number of living organ donation cases received by the HTA, compared to the corresponding quarter of the previous year.</td>
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<td>76.</td>
<td>The percentage of cases which required panel consideration had also increased.</td>
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<td>77.</td>
<td>A paper on the options for interviewing donors and recipients based in different parts of the UK would be brought to the Authority in due course.</td>
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<td>78.</td>
<td>There were plans to establish a private living lung donation programme at a UK hospital. The HTA had provided information of the requirements under the Human Tissue Act 2004 and associated Regulations.</td>
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<td>79.</td>
<td>The HTA had confirmed to a television production company that Independent Assessments could not be filmed.</td>
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<td>Item 14</td>
<td>Communications Evaluation Report Q3 [paper: HTA(19/13)]</td>
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<td>80. The Authority noted the content of the report.</td>
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<td>81. Shaun Griffin introduced the report which was the first in this format and would become a regular quarterly agenda item.</td>
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<td>82. The responses to the Arms’ Length Bodies review consultation had been overwhelmingly positive about the HTA. Of the 109 responses, only 7 were negative towards the HTA or supported the proposed transfer to the CQC.</td>
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<td>83. Steps were being taken to ensure greater granularity in enquiry logging processes and the subsequent reporting.</td>
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<td>84. The Authority noted the content of the report.</td>
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<td>Item 15</td>
<td>Strategic Performance Review February 2013 [paper: HTA(20/13)]</td>
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<td>85. Allan Marriott-Smith introduced the paper which updated Members on the progress against Key Performance Indicators.</td>
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<td>86. Members noted the low attrition and vacancy rates and congratulated SMT on these.</td>
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<td>87. The Authority noted the content of the report.</td>
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<td>Item 16</td>
<td>Finance Report February 2013 [paper: HTA(21/13)]</td>
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<td>88. Sue Gallone introduced the paper which provided Members with the financial position as at end February 2013.</td>
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<td>89. The forecasted overspend would be smaller than expected, at approximately £600k. The overspend this year was due to re-payment of reserves to DH and the subsidy of fees for the organ donation and transplantation sector, which had been met from HTA reserves.</td>
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<td>90. In real terms, this meant that the HTA would spend around £200k less than expected during 2012-13. As this is a relatively small amount, the HTA would not credit establishments with unused fees this year.</td>
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<td>91. The Authority noted the content of the report.</td>
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<td>Item 17</td>
<td>Any other business</td>
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<td>92. A panel of three Authority Members had reconsidered a living organ donation case on 15 March. A review of the process and procedures supporting reconsiderations of</td>
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<td>this nature would be undertaken to refine and improve systems, where necessary.</td>
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<td>93. Work had been undertaken on the action the HTA would be required to undertake to ensure it was fully compliant with the recommendations of The Mid Staffordshire NHS Foundation Trust Public Enquiry Report.</td>
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<td>The meeting closed at 12.15pm</td>
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