

Minutes of the meeting of the Human Tissue Authority (HTA) Board

Date: 21 September 2023

Time: 10.00 – 12.00 hrs

Venue: 2RP

Meeting Number: 105

Attendees:

Board Members

Lynne Berry, HTA Chair (LB)

Tom Chakraborti (TC)

Gary Crowe (GC)

Helen Dodds (HD)

Deborah Bowman (DB)

Ellen Donovan (ED)

Andy Greenfield (AG)

Dave Lewis (DL)

Dylan Parrin (DHSC)

HTA Executive

Colin Sullivan, Chief Executive (CS)

Louise Dineley, Director of Data,
Technology and Development (LD)

Nicolette Harrison, Director of
Regulation (joined remotely) (NH)

Tom Skrinar, Director of Finance and
Resources (TS)

John McDermott, Deputy Director for
Performance and Corporate
Governance (JMD)

Heather Troy, Board Support

Observers:

Sam Mortimer, Project Manager

Item 1 – Welcome and apologies

1. The Chair welcomed Board Members, HTA Staff, observers from the Department of Health and Social Care (DHSC) to the 105th meeting of the HTA's Board.
2. No apologies were received from Board Members.

Item 2 – Declarations of interest

3. The Chair asked Members to let the Private Office know if they have any personal or pecuniary interests and to make sure the Private Office is kept informed.
4. The Board noted new declarations of interest for a Board Member (though no conflicts were thought to arise), and that the Private Office has updated the HTA records accordingly.

Item 3 – Chair's Report

5. The Chair summarised her recent activities, which were as follows: -
 - Regular meetings with the CEO and members of the SMT.
 - Occasional meetings with DHSC (Department of Health and Social Care).
 - Carrying out long and short listing for new HTA Board Members with DHSC and an external interviewer in July, followed by three days of formal interviews in August. Recommendations for appointments have been sent to Ministers.
 - Attending a meeting with the Medicines and HealthCare products Regulatory Agency (MHRA) and other health regulators about recommendations in the McLean and O'Shaughnessy reports. The reports focused on better collaboration between regulators, raising the burden of regulation caused by duplication, increasing the focus on exchanging information and creating joint standards in regulation processes.

- Meetings with the Association of Chairs of Public Bodies set up by the Institute for Government about the Government's reform and regulation agenda.

Item 4 – Update from Department of Health and Social Care (DHSC) Sponsor Team

(DP left at 11am)

6. Dylan Parrin (DP), DHSC gave an oral update noting that he had to withdraw to attend an urgent ministerial meeting later during the agenda.
7. He highlighted that Ministers are focusing on delivering the government's agenda and ensuring resources are deployed to top priority areas. The departmental Reform and Efficiency Programme is being implemented at pace. Targets for overall staffing levels have been reached but there is still a lot to do around the prioritisation of resources between teams in DHSC.
8. The Health Ethics branch has a new deputy director. Maria Nyberg, has moved to lead a new separate branch dedicated to the infected blood inquiry. She is replaced by Amanda Davies who has a wealth of experience across government. She has met with the HTA's Senior Management Team and is keen to learn more about the work of the HTA, and any resources it needs.
9. DP and Jacky Cooper now have responsibility for sponsoring the Independent Inquiry into the issues raised by the David Fuller case.
10. DP is undertaking a consultation about a duty for clinicians to report to the HTA about any suspected transplant-related offences, as well as having a requirement to notify about transplants which take place outside of the UK. DHSC are working with the HTA's executive team to implement the necessary processes that should be followed when using the information received as part of this duty to report.
11. The DHSC has a good collaborative and supportive working relationship with HTA colleagues at all levels.
12. The Chair thanked DP and the DHSC for their help and support with recruiting new Board members. There is a list of suitable candidates, which will be looked at again after recess.

13. The report was noted by the Board.

Item 5 – The Chief Executive’s Report

14. The Chief Executive, Colin Sullivan (CS), introduced the report which aims to inform the HTA Board of key or current issues. The report covers the main issues in Quarter 1 (Q1) and some of things being worked through in Quarter 2 (Q2).
15. CS reported that Ministers have decided to reduce the GiA settlement available to HTA over the next two years which will mean the HTA will have to review and increase fees above inflation to cover costs. As part of the wider Reform and Efficiency agenda, the HTA is moving to HR shared services with the Care Quality Commission (CQC) to reduce costs/improve resilience.
16. CS spoke about the progress being made to progress regulatory and related activities against the Key Performance Indicators (KPIs). He mentioned pressure points in workload, for example, the work to support the David Fuller Inquiry led by Sir Jonathan Michael and the increased activity for HTA on the Living Organ Donation front, in part due to last year’s changes to Section 32a of the Human Tissues Act (2004).
17. The increase in police referrals is adding to the increase in pressure on staff at the HTA. Therefore, CS is seeking subject to resources being available, to review the role of the Independent Assessors (IAs) and the overall approval process to both improve the approach where possible and streamline approaches to help ease pressures.
18. There has been a notable improvement from 2022 in terms of the audit outcome regarding the Data Security Protection Toolkit (DSPT). The final outturn reported at the end of Q1 was “moderate” which was a great achievement.
19. CS also mentioned that in Q1 (both in June and again in early September), the HTA published additional data sets in keeping with its aim of being a transparent regulator.

20. HD congratulated LD on the improved outcome regarding DSPT and asked what the next steps are. In response, LD thanked her Project Manager, for her hard work that has more than contributed to this improvement in outcome. The aim is to maintain the progress made, DSPT standards change year on year, so that would be a good achievement.
21. DL asked for more information regarding Paragraph 5 in the CEO's report regarding Living Organ Donations, where it states that the HTA are in discussion with the DHSC Sponsor team about supporting the police when there are breaches of Section 32.
22. CS explained that in July 2022, changes were made to Section 32 whereby it is now an offence to seek an organ inappropriately without proper consent, duress and reward. This has led to an increase in the number of cases which in turn has led to more time consuming police referrals. GC stressed it is important to record the impact of these changes to Section 32 on the HTA's workload.
23. There was a discussion about paragraph 16 which states that in the last Autumn statement, the Chancellor announced a Pro-innovation Regulation of Technologies Review (led by Dame Angela McLean) to advise how the UK can better regulate emerging technologies. Further to participating in a cross regulatory session led by the Chair and Chief Executive of the MHRA in July 2023, the HTA is engaging in activities to implement actions suggested in the Pro-innovation Regulation of Technologies Review in collaboration with other ALBs.
24. The Chair noted the HTA had a duty to respond to the McLean Review and agreed with GC that this is detailed work requiring focus and is in addition to existing BAU and project work. Therefore it adds to work pressure.
25. DB asked how the leadership team were prioritising work and projects when resources are so stretched. CS replied that the monthly portfolio management process tracks the progress of delivery against the HTA's Business Plan and looks specifically at performance in terms of BAU and projects and what resources they require. CS noted that when there is pressure in-year certain projects have been de-prioritised and pushed back.
26. The Board noted the report.

Item 6 – HTA Performance Report

27. The Chief Executive, Colin Sullivan (CS) introduced the report and provided highlights to Members of Performance in Q1 against the HTA's objectives and operational delivery targets. He noted all business as usual (BAU)/operational targets were green at Q1 and on track, but several projects were behind.
28. CS outlined some key work happening within the policy and development space. There are 2 key projects, Assessing our Impact and Establishing the Insight Network.
29. CS spoke about work the Communications team have been undertaking to support the delivery of core business. The cost of changes to the HTA's website to meet accessibility requirements as identified by the Government Digital Services (GDS) have been relatively high for a small organisation.
30. CS reported there wasn't any unscheduled downtime or system loss, even though there was a lack of available IT expertise during the summer due to the absence of the Head of IT. During the consideration of IT resourcing, the Board noted that a new Head of IT will join the HTA in November 2023.
31. HD asked what the timeline for the Insight Network project is, and LD replied she will take a proposal with a proposed list of members to start the group to SMT in the next couple of weeks.
32. ED asked if Freedom of Information Requests (FOI) are analysed, and JMD confirmed they are.
33. TC asked if CS was concerned about the forthcoming change in grant and aid (GiA), and the need to increase stakeholders' fees. CS replied an increase in fees is a general trend across all regulatory bodies, other ALBs are in a similar space. He also noted costs which have escalated such as IT costs, increases in inflation must be covered as well. He outlined that the DHSC would still be providing some GiA and there are some items that could not be charged to establishments as they covered HTA work that didn't benefit licenced establishments.
34. GC was concerned that the HTA is now behind on its projects, and its risk ratings are increasing. CS responded some project work has been carried out

successfully, for example, significant changes have been made within the area of inspections/regulation and as a result the approach to inspections is now more bespoke. The Chair praised the creative energy and hard work that is going into managing projects and development work at HTA.

35. The Board noted the report.

Item 7 – Innovation in Inspection

36. Nicolette Harrison (NH) presented the paper which provided an update on the progress being made by HTA to innovate its approach to inspection through the Review of Inspection Project and the development of Evaluated Self-Assessments (ESAs). The approach to these projects has been agile, with small pilots being run first to ensure the innovations are balanced and in line with strategy.
37. NH pointed out the figures for the number of inspections in 2022/2023 compared to 2018/2019 was 243 (nearly a 40% increase) when licence application assessment visits (LAAVs) were included in inspection numbers.
38. There was a discussion about the proposed next steps, building on Phase 1 of the Review of Inspection project and the ongoing development of ESAs. HD asked about 9a which states that post-inspection activity amounted to up to 60% of the time spent on inspection-related activity, she asked is this more time spent than previously and is there any indication what is driving these short falls?
39. NH responded it is similar to the level of activity shown in an informal survey carried out in 2019/2020. There are now significantly more inspections in the PM sector, partly because of the pandemic which has meant that a lot of premises hadn't been inspected for a while.
40. DL asked how any risks around using Evaluated Self Assessments (ESAs) are being managed. NH replied VRAs are used in the research sector, where there are very few inspections over the year. ESAs are a mixture of self-assessment and a risk profiling tool. When an ESA is carried out, and there are concerns, a full inspection is then scheduled to follow. There is a well-established scheduling process lead by the Head of the Regulatory Operations Team.

41. Risk scheduling is not just a reaction to immediate concerns about an establishment, if there are concerns about an establishment these are fed into the process. NH added that the development of RIMI (Regulatory Insight Model and Index) should enhance the already established scheduling process
42. DB commented on paragraph 14, and asked how change fatigue is managed when new pilots are being run to test new innovations and staff are juggling this with BAU work. NH responded the executive team are keen to encourage regulatory staff to put new ideas forward because these staff provide a good inspiration for new innovations, for example, the ESAs emerged from the team of the Head of Regulation for Research and Anatomy.
43. CS reminded Members that next year the Executive Team will recommend which innovations will come for approval in the Business Plan. The development of some projects such as the ESAs is ongoing, whereas other projects such as the Review of Inspections have been paused.
44. The Chair thanked NH and her team for all of their hard work looking into innovations in inspections and restated the Board's concern about the pressure on employees and change weariness.
45. Members noted the content of the report.

Item 8 – HTA Standing Orders

46. As part of HTA's governance cycle HTA's Standing Orders are reviewed every 2 years for accuracy. As they were last approved in October 2021, during Q1 a comprehensive accuracy review of the Standing Orders was undertaken with BDT, SMT and ARAC Members. The changes are listed in Annexes A and B.
47. JMD stated there are 2 further changes to make, under Annex B, the next review date should be in October 2025. An amendment is also needed to Annex B, Paragraph 43 and the reference to the Staff Forum.
48. The Board approved the updated Standing Orders (at Annex A) to include the two final changes noted above.

49. **Action:** JMD to make the changes to the HTA Standing Orders as detailed above.

Item 9 – Data and Digital Update – Louise Dineley

50. LD gave an update on the strategic direction of digital and data, including the progress made against the 2023/24 Business Plan. At the meeting in March 2023, the Board approved the 2023/24 Business Plan which identified a commitment to explore a shared service model for future IT provision.
51. The HTA wants to do more with data sharing and collaborative efforts, however, as a small organisation, it has been difficult to secure sufficient funding and resources for IT. A few achievements that have been made are the first phase of moving to an Electronic Document Management System (EDRMS) has been completed, also the way data is used has been developed to give greater insight in terms of the HTA's impact and how it responds to emerging areas of risk.
52. The HTA is exploring a national data repository with NHS England (NHSE) and working on the complaints review with Medicines and Healthcare Products Regulatory Agency (MHRA). LD added that any plans for development must take account for valuable collaborations such as these. On November 1st, a new Head of IT will begin work.
53. Work is being done to strengthen the use of data as part of the HTA's day to day operations, and there have been 2 planned publications of HTA datasets since April 2023. Scrutiny of data sets has helped to identify themes and trends to look at the impact of HTA's activities and inform innovative new ways of working.
54. LD thanked Sam Mortimer, Project Manager for all her work on the RIMI project, which began in Q2. Whether or not this continues is dependent on DHSC approving the business case. LD added that SMT have concurred that a transition to IT Shared Services is not affordable at present.
55. CS stated he has written to the Permanent Secretary and the Chief Executive of CQC stating that a transition to IT shared Services would need to be centrally coordinated across the ALBs.

56. HD referred to Fig 1, HTA Data and Digital Vision, and asked how much progress the HTA has made towards fulfilling that vision, also what part it would play in relation to Artificial Intelligence (AI). LD reminded Members that there have been limited resources in IT for about 15 months. She has been delivering the IT service on her own with the support of BCC but is hopeful that when the new Head of IT starts, they will have time to focus on and deliver the vision in Fig 1. LD invited Members to join a Lunch and Learn Session about AI on 4 October, she added the HTA is not engaged in any work specifically around AI at present.
57. GC asked for an explanation about the business case referred to. LD replied the business case is for the development of RIMI, which links in with the national data repository being led by NHSE, who are trying to get all ALBs to include their information. She is working through and discussing this with them.
58. Members noted the report.

Item 10 – Outline and introduction to the revised strategy

59. LD presented this paper which provided members with an overview of the HTA's current strategy and the process for reviewing and updating the strategy, with the timescales highlighted. He gave a summary of what was being considered. The paper sought to provide an update on emerging themes and the new landscape.
60. The Outline and Introduction to the Revised Strategy and the timeline for updating the strategy was noted by Members

Item 11 – Remuneration Committee Update – Ellen Donovan

61. ED gave a brief update regarding the RemCo meeting held on 13 September 2023. 3 key items were discussed: -
- a. HR Shared Services.
 - b. Remit of RemCo. RemCo has 2 responsibilities, a formal governance role to agree the remuneration strategy on behalf of the Board, and to act as advisor/sounding board for the Chief Executive.

- c. Executive Senior Managers' (ESM) pay. The committee considered a paper on ESM pay which was approved. The pay award for all staff was approved at the last RemCo meeting.

62. ED thanked DB for her attendance and huge contribution to the Committee meetings.

63. Members noted the Committee Update.

Item 12 – Minutes of 29 June 2023

64. The minutes of the Board meeting on 29 June were distributed to Members, with a deadline of 25 August for any amendments or changes. There was 1 amendment, Jacky Cooper observed the meeting virtually and she submitted a paragraph to the Chief Executive which was read out.

65. Members accepted the minutes as a true record of the Board Meeting Conducted in Public on 29 June 2023

Item 13 – Matters arising from 29 June 2023

66. There were no actions arising from the previous meeting.

Item 14 - Any other business

67. There is currently a national campaign regarding 'sexual harassment at work', GC asked what HTA is doing to engage staff regarding this. CS replied, there is zero tolerance of this behaviour at the HTA, and staff are encouraged to either speak to their line manager, or if that is inappropriate, to talk to another manager or the Staff Speak Up Champion, if they feel victimised in this way or any other way.

68. As it was her last Board meeting, the Chair thanked Deborah Bowman for her huge contribution to the Board and RemCo, she will be missed, and wished her well for the future.

Date of next meeting: 7 December 2023 at 2 Redman Place.