

HTA Board meeting, 18 September 2025

Agenda item	2.5 - Chief Executive's Report
For information or decision?	Information
Decision making to date?	N/A
Recommendation	The HTA Board is asked to note and comment by exception on the issues raised
Which strategic risks are relevant?	Risk 1: Operational Risk 2: Reputational Risk 3: Financial Risk 4: Strategy Risk 5: People Risk 6: Security
Strategic objective	Efficient and Effective
Core operations / Change activity	Core operations
Business Plan item	Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including risk management and seeking opportunities for ALB collaboration)
Committee oversight?	Board only
Finance and resource implications	Various due to the range of items covered
Timescales	Various due to the range of items covered
Communication(s) (internal/external stakeholders)	N/A
Identified legislative implications	N/A

Chief Executive's Report

Purpose of paper

1. To inform the HTA Board of key or current issues from the CEO's perspective.

Action required

2. The HTA Board is asked to **note** and comment on the issues raised.

Update on Quarter 1 of 2025-26

3. During Q1, we continued to progress our regulatory and related activities against the Key Performance Indicators, sought to progress the early aspects of the 2024/25 Business Plan, and responded to matters arising.
4. From a strategic perspective, during the first months of 25/26, several important government reforms and initiatives were announced in the health sector and more widely across government. These include:
 - ALB Landscape Review – 7 April 2025
 - Spending Review 2025 – 11 June 2025
 - 10-year Health Plan for England - 3 July 2025
 - Dash Report – 7 July 2025
 - Life Sciences Sector Plan – 16 July 2025
5. These announcements follow the earlier decision that our host department is to be merged with NHS England and restructured. The reformed department is seeking to work in different ways with the health sector. We are striving to align fully with this package of reforms and to progress those elements which fall to or include the HTA. We are also endeavouring to work in concert with reform initiatives by the Devolved Administrations and have been keeping in touch with relevant officials. Working to assist our staff with these reform changes has been one key and early element of our People Strategy and during Q1 we ran training sessions for all staff and line managers covering “Ready for Change” and “Supporting our people through change”. Later on the agenda, we provide a paper highlighting to the Board how we are responding to these multifaceted reforms.
6. Data Collection Exercise (DCE): The HTA completed a comprehensive DCE with all licensed establishments in five of our six sectors, providing insight to a small number of key risk areas. By incorporating lessons learned from the

previous exercise in 2023/24, this year's exercise was completed on time with a very high return rate (96%) by deadline and subsequently we received 100% of the returns. The data are now being utilised in risk scoring using Power BI, to help inform the HTA risk assessments. A smaller and more focused exercise was carried out in the Human Application (HA) sector, specifically targeting additional information required in relation to certain preparation processes (the processing methods used by establishments prior to the storage and/or human application of tissues and cells). The DCE was an efficient and effective means of gathering and utilising sector and establishment risk data at low cost to the HTA and establishments and provided another opportunity for a touch point with licensed establishments, especially those in sectors for whom inspections are less frequent.

7. During the three months of Q1, I have continued to have a series of external meetings and attended a number of relevant seminars. I would especially draw attention to the Health & Social Care Regulators Forum which includes regulators of both institutions and care professionals. It is a helpful network and also the forum for an "Emerging Concerns Protocol" where any matters of concern to one regulator can be documented and shared with others. The HTA joined about 18 months ago and has become an established member.

Current Issues

8. Board members are already aware that the final report of Sir Jonathan Michael's Inquiry into the offending in a hospital mortuary by David Fuller and the wider strategic picture regarding care of the deceased was published on 15 July. The report includes 75 recommendations and a Written Ministerial Statement (WMS) to the House of Commons by the Secretary of State (and by the Health Minister, Baroness Merron, in the House of Lords) was published on the same day.¹ It noted that, *'The overall conclusion of today's final report is that current arrangements for the care of people after death are partial, ineffective and in some areas, completely lacking'* and committed to responding with an interim update on progress this year and a final response by Summer 2026.
9. The HTA is now supporting DHSC as work is progressed to consider the recommendations and support Ministerial decision-making. A dedicated paper is provided later in the meeting for the Board to consider but I wanted within my CEO report to thank all those in the HTA who have worked hard behind the scenes to support the Inquiry and to those who have, in parallel, been working to develop and enhance our regulatory activities for the care of the

¹ [Fuller Inquiry Phase 2 Report - Hansard - UK Parliament](#)

deceased. I was very pleased that the Inquiry's Final Report recognised the notable progress made by the HTA.

10. During July, the Comptroller and Auditor General (C&AG) at the National Audit Office (NAO) certified the HTA accounts for 2024/25 and they were laid before Parliament on 17th July, ahead of the summer recess. This is a significant piece of work, not least for a small organisation and I am very grateful to the Finance team who provided great support to me as Accounting Officer. The draft Annual Report and Accounts (ARA) were considered by the Audit and Risk Committee (ARAC) at the June meeting.
11. Business Plan for 2025/26 – Board members will recall viewing and commenting upon the draft Business Plan at the Board meeting in March. It was subsequently submitted to DHSC for approval and has been formally approved. We may need to revisit the plan in-year as DHSC has recently asked that all its Arm's Length Bodies adopt spend controls (RDEL – Resource Departmental Expenditure Limit) over the remainder of 2025-26, as have been introduced by DHSC. These include certain staff costs and non-staff costs that are not already committed without a legal or other binding commitment. We are actively working through this issue at present and the impact it might have on us.
12. In early September we published the Annual Review of 2024/25 sharing highlights and achievements from the last 12 months. The review sets out our approach to regulation and activities over the last 12 months including the use of targeted assessments, an analysis of shortfalls identified and incidents reported by sector and the strengthening of our use of data to support wider regulatory activities and the maintenance of a risk-based approach. The review has also reflected on strategic change in the system and how innovation and growth in life sciences and emerging technologies may lead to further changes in the next 12 months.
13. Living Organ Donation (LOD): The HTA has recently been informed by the police of the outcome of their investigation into a prospective living organ donation that had been submitted to the HTA for approval but that we did not approve. The HTA referred its concerns about potential offences under s32 Human Tissue Act 2004 of 'commercial dealing in organs' to the police for further investigation. The police investigation has now concluded and an individual has accepted a caution for the offence of giving/receiving reward for the supply/offer of human material for transplantation.
14. From 1 July 2025, the duty on clinicians working in the organ donation & transplantation arena to report to the HTA cases where organ transplants take place outside the UK, or where a clinician has a reasonable suspicion that an

organ donation and transplantation related offence may have been committed has been extended to Scotland. This is under The Human Tissue (Supply of Information about Transplants) (Scotland) Regulations 2025 and as a result the whole of the UK is now covered by similar legislation. The HTA has had the same role since 1 April 2024 in England, Wales and NI. The greater population coverage may result in additional cases being referred to us by clinicians. In the first two months since the law change we had no referrals from Scotland and the overall flow remains in the region of between three to six cases per month, with an average of 3.25 reports a month in 2024/25 and a higher average of 4.6 reports a month in the five months to 31 August 2025.²

15. We launched a short pulse survey in July as the first of our People Strategy related surveys. This covered seven questions and ran from 7-15 July. We received a very encouraging high response rate with over 80% of our staff responding. Almost everyone said that they were positive about the support provided from their line manager and 77% thought that communication regarding the People Strategy had been good. However, about a quarter (26%) are still to be convinced that the People Strategy is going to make the positive difference to working for the HTA and we recognise that there is still work to do in supporting changes and positive improvements throughout the organisation. Other responses regarding decision-making, development and having a good work/life balance were roughly in line with the responses two years ago, and are closely linked to the work taking place in developing a leadership programme for all HTA managers. The responses in the pulse survey gave a good indication of what people were feeling at that moment in time and overall a good set of results that we will compare at the end of Q2 and build on further as we progress the People Strategy.
16. As part of our engagement and development activity with key actors in the sectors we regulate, we have arranged a Learning Event on 19 September. This is designed to enable engagement and learning exchanges between the HTA and representatives from each of the six sectors we regulate. At the event, we will cover the HTA's Review of the 24/25 year and seek feedback from Designated Individuals (DIs) and other principal players, across each of the sectors we regulate.
17. The next HTA Board meeting will be held on Thursday 4 December 2025.

Recommendation

18. The HTA Board is asked to **note** and comment on the issues raised.

² 39 reports received in 2024/25. 23 reports received in the five months to 31st August 2025.