

HTA Board meeting, 6 March 2025

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| Agenda item | 2.3 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: Regulation Risk 2: Sector Risk 3: Staff Risk 4: Financial Risk 5: Digital |
| 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 3

3. During Quarter 3, we progressed our regulatory and related responsibilities and responded to matters arising.
4. Within the Post Mortem sector, during Q3 and into Q4, we have continued with our programme of unannounced inspections, with 19 completed by mid-February. We believe this approach has been successful in terms of driving consistency in compliance. Examples of shortfalls discovered that would otherwise have gone undetected include insecure premises, insufficient storage and the absence of a Designated Individual (DI) who had left and not been replaced.
5. In parallel, we have continued to support the Inquiry by Sir Jonathan Michael into the issues raised by the David Fuller case. The final report (Phase 2) of the Inquiry, which considers the system wide approach, is expected to be published mid-2025, and the HTA will work to assist implementation of those recommendations that are supported by Ministers.
6. In relation to Living Organ Donation (LOD) activity, over the first three-quarters of 2024/25 to December 2024, the HTA approved 855 cases of living organ donation. Of these 27% were approved by the Board, whilst the remaining 73% were assessed and approved by the HTA's LOD team.
7. The HTA has continued to receive a regular flow of cases under The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024 which require relevant clinicians to report all organ transplants that take place outside the UK, or if they have a reasonable suspicion that an organ donation and transplantation-related offence may have been committed. Any anticipated drop in the number of cases, following an initial flurry of more historic cases at the outset, has not materialised. As of 14 February, we had received 37 reports, averaging 3.5 cases per month or almost one per week. We also continue to receive a number of reports that pre-date the introduction

of the regulations. Each of these cases requires consideration as to whether further action, including referral to the police, is warranted. At the end of Q4, the regulations will have been in place for one year and we will conduct a review of our implementation of the regulations and plan to update the Board at the June meeting.

8. On 6 December, I spoke at an organ trafficking conference organised by the Metropolitan Police. This followed on from a similar conference held in January 2024. These events have been invaluable for strengthening linkages and improving understanding between the different agencies involved in countering organ trafficking.
9. As the Board is aware, EU Regulations regarding substances of human origin (SoHO) intended for human application were published in 2024 and will come into effect in August 2027, following a three-year transition period. The Regulations apply to all HTA establishments in Northern Ireland and extend the scope of tissues and cells that require regulation and activities that would require a licence. We continue to assess the implications for our NI licensed establishments to ensure the transition is managed effectively and that standards of safety and quality for substances of human origin are not compromised. We also continue to:
 - a) support the Department in its evaluation of whether changes to existing UK legislation may be required, and
 - b) engage with the Department and other relevant regulators to discuss and understand the impact of these regulations.

Current Issues

10. In Q4, we have been refining our Business Plan for 2025/26. During next year, we will continue to prioritise frontline delivery, which involves maintaining regular touch points with our licenced establishments through proportionate and risk-based regulation (by undertaking inspections and other regulatory assessments).
11. IT development is another area recognised as a priority for investment. Cyber Security is a constant threat and whilst the HTA has good assurances around our practices, the need to continue investment and modernisation within this space remains a key focus. We need to ensure that all Core Essential Functions within the HTA remain supported and protected, consistent with the new Cyber Assessment Framework (CAF). The strategic themes within the Digital & IT Strategy around Resilience and Availability drive forward the

ambition to evaluate emerging technologies in a constantly changing landscape. Our prioritisation of certain areas does mean deferring some others we would have liked to pursue in the next year's Business Plan which is presented to the Board at today's meeting.

12. Board members will recall discussions at the December meeting about the HTA's budget for 2025/26 and the fees required to ensure our income balances necessary expenditure. In recent weeks, our budget for 25/26 has been agreed by DHSC. However, there is more work to do in relation to both resource and capital spend in preparation for the Spending Review. In Q4, we have also been working to improve our efficiency and effectiveness. This includes looking at ways of reducing inputs for a similar level of outputs, work which will continue during 2025/26 to help reduce work pressure on staff whilst meeting our obligations. A reduction in the number of desks used by the HTA in 2 Redman Place will help with a recurrent saving without putting service delivery at risk.
13. As Board members will be aware, the annual Board Effectiveness Review (BER) is ongoing, and as well as the Board, also takes account of the effectiveness of the ARAC and RemCo sub-committees. With an external BER having been undertaken last year by independent consultants, the Chair has asked this year for a lighter touch internal BER exercise in Q4 which will focus on:
 - The Board dynamic, its behaviours, and relationships with the executive.
 - The Board's balance of skills and experience, along with how these can be best deployed and developed.
13. During Q4, work has progressed to bring together the views and contributions from staff, all across the HTA, into a coherent and practical 3-year People Strategy. An early draft of the document was discussed at RemCo in January. We have further refined the strategy in February and today the full Board today has the opportunity to discuss the strategy. Flowing from the strategy, we have started developing an implementation plan for prioritised actions and aim to discuss present this plan at the next RemCo meeting in May.
14. I should also highlight to Board members that the 2026 Board meeting schedule has been agreed by our Chair to be:
 - Thursday 5th March 2026
 - Thursday 25th June 2026
 - Thursday 17th September 2026
 - Thursday 3rd December 2026

Recommendation

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