

HTA Board meeting, 26 June 2025

Agenda item	3.2 – HTA Strategy 2024-27: our review of year one
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 review
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?	N/A
Finance and resource implications	As per HTA Business Plan 2025/26
Timescales	Annual review
Communication(s) (internal/external stakeholders)	Not applicable
Identified legislative implications	Not applicable

HTA Strategy 2024-27: our review of year one

Issue

1. In August 2024, the HTA published its Strategy for the next three years setting out its ambition against four priorities:
 - our approach to regulation;
 - the use of information;
 - building trust and confidence and
 - being efficient and effective in the delivery of our activities.
2. This paper covers reflections on the first year of the Strategy, the successes, learning and insight from our delivery and impact of changes in the external landscape and how these may shape and inform future delivery of safeguards to the use of tissues and cells and the effectiveness of the HTA as a regulator.

Ask

3. The Board is asked to **note** the report on the activities delivered during 2024/25, the first year of the HTA's Strategy.

Overview of the HTA Strategy

4. The HTA Strategy has a clear vision - the safe and trusted use of human tissue - and an unequivocal mission to be an excellent regulator sustaining public and professional confidence, today and in the future.
5. In the 20 years since the HTA was established many practices in the use of tissues, cells and organs have changed, but the importance of consent remains a core principle in our approach and our goal to provide public trust and confidence.
6. Our strategy recognises the quickening pace of change, innovation and improvements in all sectors and developments on the periphery of current regulation.
7. Our four strategic priorities form the framework for our annual business planning process, which aligns with the resource envelope we operate within. The Business Plan for 2024/25 represented year one of our three-year Strategy, in which we are seeking to develop the capabilities necessary to deliver on our Vision and Mission in the most innovative, effective and value

for money ways possible.

8. In our first year implementing the strategy, we have made good progress in delivering against our four strategic priorities, as outlined below.

Approach to Regulation

9. We have continued to deliver high inspection numbers, completing 223 inspections in 2024/25, against our target of 222. Of these 25 were unannounced. The mix of inspections included:
 - 100 full inspections
 - 93 focused inspections
 - 13 Establishment Site Assessments (ESAs)
 - 17 Other types including the follow up of previous Corrective and Preventative Actions (CAPAs)
10. In addition to these inspections, carried out 28 new licence application assessments and processed 874 variations and updates to existing licenses, helping new establishments comply with all our licencing standards and ensuring they start on a sound regulatory footing. A further 158 Evidential Compliance Assessments were completed in the Post Mortem Sector, a new assessment tool that led to a number of inspections.
11. Our collaborative approach has been evident in the preparation for the implementation of the Regulation on Standards of Quality and Safety for Substances of Human Origin (SoHO) in Northern Ireland. We have established a multiphase project, with the first 'scoping' phase focusing on a gap analysis between existing and new requirements, and collaborative working across the health system.
12. We have also played a key role in detecting human trafficking for organ removal through our work approving living organ donations and considering all cases referred to the HTA following the introduction of the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024, placing a duty on 'relevant' clinicians to inform the HTA of specific matters concerning transplants overseas and suspicions of transplant-related offences.
13. For 2025/26, we are focused on achieving the challenging key performance indicators that we have set, including a programme of 222 compliance assessments on existing licences, across all sectors, in addition to demand-led new licence application assessments. In addition, we will evaluate our implementation of the HTA 2004 (Supply of Information about Transplants)

Regulations 2024. We will continue to explore how we might further strengthen our processes for Living Organ Donation approvals.

Use of Information

14. We have invested in our IT systems using the opportunity to enhance our digital capacity and capability with an upgrade to our CRM system. In March 2025, we launched our new Regulatory Insight Model & Index (RIMI), a significant advance in how we interrogate data. This internal tool uses data since 2017/18 on six key indicators taken from our regulatory activities, providing greater insight into both individual establishments and trends in the sectors we regulate.
15. We also introduced a new horizon scanning process to be more aware of and responsive to emerging scientific and technological developments and innovations. Our first annual horizon scanning report was presented to the Board in March 2025, identifying high-priority topics that have informed our work and resource allocation for 2025/26.
16. During 2025/26, we will implement a Change Authority Board process so that new ideas and developments to systems and practices can be appropriately considered and managed to build our digital capability and capacity. We will continue to ensure our technology and data are stable and robust, maintaining 99% system availability across our core essential functions and publish open datasets twice a year.

Building Trust and Confidence

17. Our work continues to help strengthen public trust and confidence through our licencing, inspection, and authorisation processes, and by being open and transparent. We have published open datasets on inspections, shortfalls, incidents, and enquiries, increasing transparency and enabling the public to see how effectively the HTA is regulating.
18. We have been involved in emerging areas that present unique regulatory challenges, such as Xenotransplantation, which could help address the global shortfall in donated organs. Through a co-sponsored (DHSC & NHSBT) Xenotransplantation steering group, we have shared our experience and insights to inform future regulation of this emerging area.
19. Our communication and engagement programme in 2024/25 included a quarterly newsletter reaching over 10,000 subscribers, sector-focused forums for Post-Mortem, Anatomy, and Research, refreshing our working

relationships, including updating and developing Memorandum of Understandings with key partners across the system and a learning event attended by professionals from across the sectors we regulate. The September 2024 event received excellent feedback, with 96% of attendees saying they would be likely to attend our next event. The roundtable discussions were particularly appreciated, providing an opportunity to share experiences, discuss challenges, and learn from others within their sectors.

20. For 2025/26, a key focus will be to initiate a review of our Codes of Practice to ensure they are reflective of best practice. This work is likely to lead to a significant programme across multiple years, but the aim in 2025/26 is to complete an initial review and identify where changes are necessary. We also have a learning event planned for September 2025 which builds on feedback and will include a blend of engagement and learning opportunities

Efficient and Effective

21. We have continued to strive to deliver a proportionate yet robust approach to regulation in the most efficient and cost-effective way. An example of this is our work on the licensing requirements associated with the storage of certain types of products. Working with a specialist supplier, we were able to agree an extended period of end-use storage that was not subject to licensing under the Human Tissue (Quality and Safety for Human Application) Regulations, 2007. By removing the need for an end-user licence, in very specific circumstances, we were able to address logistical challenges associated with 'just in time' supply models, while not increasing risks to patients.
22. Underpinning our delivery is the vital role our colleagues at the HTA play, which we have recognised through the introduction of a new People Strategy to support the development and retention of our most valuable asset. In addition, our three-year Digital & IT Strategy is driving forward improvements in the delivery, management, and compliance of IT Systems across the HTA, with a focus on excellent Cyber Security and secure IT Systems.
23. For 2025/26, we will embark on two major change initiatives: replacing our finance system with a solution that has better functionality and implementing our new People Strategy, to ensure we are supporting and rewarding our colleagues. As stated in our 2025/26 Business Plan, we are challenging ourselves to fulfil our role efficiently and effectively and we commit to working with government to contribute savings in-year and to support wider initiatives as best we can.

Summary

24. The first year of our strategy implementation has coincided with changes to the external landscape with the potential for changes to be more widespread over the next two years. The HTA has continued to deliver as an effective regulator of tissues and cells and by working with partners operating in the health and life sciences systems the HTA remains aware and responsive to the changing landscape. As an organisation of approximately 60 people and an operating budget of £6.4 million, our approach to delivery necessitates the need for efficient and effective use of our resources.
25. As well as delivering our regulatory activities, over the last 12 months, our supporting functions have also delivered high performance in cyber security, digital and data innovations, development and utilisation of an HR shared service, supported the introduction of DHSC secondary regulations, and provided strong communications with professionals through the targeted use of a various communication channels.

Next Steps

26. Our business plan for 25/26 sets out in detail our planned activities. These include a review of our approach to updating the Codes of Practice; continued delivery of a comprehensive programme of sector-based assessments; responding to the findings of the Fuller Independent Inquiry; development of our workforce through the delivery of our People Strategy, and continued investment in the security of our IT systems and prevention of data loss through cyber-attacks.
27. Our relatively small size means balancing resource across our priority projects, increasing volumes of complex Living Organ Donation cases (with Scotland's DTR coming into force in July) and ambitious core operational delivery is challenging. However, we aim to maintain flexibility in resource allocation, respond quickly to changes, adjust the plan throughout the year, if appropriate, and make decisive decisions to start, pause/stop, or change work as necessary.
28. We will publish our Annual Review, summarising our activity and impact during year one of the strategy. We plan to hold another learning event in September 2025, focusing on delivering the second year of our strategy. We hope representatives from a large number of licensed establishments will be able to participate.
29. We will apply the learning from our early work on the strategy to inform our

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2026/27 business plan, seeking to continue to make progress against our strategic priorities. In line with our Business Plan for this year, we will maintain flexibility in resource allocation, respond to changes, adjust the plan throughout the year, if appropriate.

Recommendation

30. The Board is asked to note the report on the activities delivered during 2024/25, the first year of the HTA's Strategy.