

HTA Board meeting, 18 September 2025

Agenda item	3.2 – Strategic Change
For information or decision?	Information
Decision making to date?	N/A
Recommendation	The HTA Board is asked to note and comment on the context provided
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	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

Strategic Change

Issue

1. Several important government reforms and initiatives have been announced in the health sector and more widely across government. These developments seek to drive growth, promote greater innovation in the delivery of regulated activities, increase responsiveness, and reduce costs.
2. The HTA has completed year 1 of its three-year Strategy (2024-27) and reviewed its strategic priorities considering external developments, delivery of statutory duties, and maintaining an efficient operating model within our 2025 Spending Review allocation
3. This paper collates and summarises these new developments and considers the implications for the HTA, its strategy and its approach to regulation.

Ask

4. The Board is asked to note the report and the summary of key strategic developments and consider the implications for the HTA.

Summary of Strategic Changes

5. The breadth and ambition of reform and strategic change is notable and is reflected in the ALB Landscape Review (7 April 2025), the Spending Review 2025 (11 June 2025), the 10-year Health Plan for England (3 July) and the Dash Report (7 July 2025) and the Life Sciences Sector Plan (16 July 2025). In tandem government initiatives and strategic positions have been highlighted in the government's Growth & Industrial Strategy and through its promotion of regulatory innovation with the establishment of the Regulatory Innovation Office (RIO).
6. The **10 year Health Plan** ([10 Year Health Plan for England: fit for the future - GOV.UK](#)) was launched in July 2025. Work commenced on this plan in the preceding Autumn and was supported by extensive consultation. The HTA shared feedback and insights from its regulatory activity on emerging themes from shortfalls and other regulatory activity. We identified opportunities for improvement and contribution to the priority areas identified in the plan and at the same time considered how we could reflect these in our delivery. The HTA's remit extends beyond the NHS and England, as such we are cognisant of the need to respond to the breadth of priorities across administrations and

the opportunities for growth and change highlighted by government and the devolved administrations.

7. Another significant announcement signalling strategic change was in March 2025, with the **abolishment of NHSE and its merger with DHSC**. This confirmed that in addition to revisions to strategic priorities in the delivery of health and social care and the life sciences, there would be notable changes to organisational form and functions within our parent department.
8. We work closely with DHSC to inform policy on matters that fall within the HTA's remit as well as from an accountability arrangement as an Arm's Length Body, with an allocated sponsor team. The relationship with NHSE has been as a system partner, working collaboratively across the health family on areas of common and overlapping interest. In the last year common interest areas have included issues related to mortuary oversight, the updating of consent processes and forms and guidance on the handling of remains following pregnancy loss. The HTA is committed to continuing to work closely with colleagues over the transition period to ensure that public trust and confidence in the discharge of our duties is maintained.
9. In parallel to the announcement to abolish NHSE, the report produced by **Dr Penny Dash** ([Review of patient safety across the health and care landscape - GOV.UK](#)), which was a review of patient safety, recommended changes to the form and function of several ALBs. These changes are ahead of any outcome of the Arm's Length Bodies Review Bill currently at its second reading in the House of Lords.
10. The ambition of these changes is summarised in **Annex A** and accompanied by a summary analysis of considerations and implications for the HTA.
11. Alongside these developments sits the **Spending Review**. Whilst the June 2025 Spending Review settlement for DHSC increased both day-to-day and capital spending for the health service, across the SR period reductions are expected in the resources available for functions at the centre (i.e. DHSC and the ALBs). The HTA receives a proportion of its budget from DHSC in the form of Grant in Aid (GiA). This has been reduced in recent years to now stand at only 5% but that figure may come under further pressure. In addition to these strategic resourcing shifts there are in-year pressures resulting in the recent DHSC moratorium on certain areas of expenditure. Such constraints highlight the importance of continuing to progress opportunities for more efficient and effective delivery of our regulation and support activities, as set out in the current HTA Strategy.
12. As well as the generic changes impacting the health ALBs, and in some

cases, the wider ALB landscape, there are other changes more specific to the roles performed by the HTA. Notable examples of these include:

- Legislatively driven change linked to business and technical advances. For example, in 2024 the HTA in conjunction with some other regulators commenced a three year programme of work to implement the new regulations covering Substances of Human Origin (SoHO) in Northern Ireland. These will become operational from August 2027. Consistent with the HTA strategy, we are seeking to progress and respond to the SoHO changes through digital solutions and proportionate regulation.
- Sir Jonathan Michael's Inquiry specifically deals with one aspect of our work, the dignity of the deceased, rather than generic reform. Nonetheless, it could lead to significant strategic changes to the HTA, depending upon which of Sir Jonathan's recommendations are accepted by Ministers. (A separate paper is provided on the agenda covering the Inquiry's final report.).

Combined strategic themes to consider for the HTA

13. Analysis of each of the initiatives listed and in Annex A above highlights a number of interconnected themes that are shaping our strategic response:
 - **Reform and Modernisation of Regulation:** Government expects regulators to move beyond traditional compliance models towards enabling innovation. For the HTA, this means further developing our risk-based approaches, exploring learning from regulatory sandboxes for emerging technologies, and demonstrating how our oversight supports rather than constrains beneficial developments in tissue and cell therapies.
 - **Digital-First Regulation:** The consistent emphasis on digital solutions across all reviews aligns with our investment in technological capacity. However, we must accelerate our digital transformation to meet stakeholder expectations for streamlined, data-driven regulatory processes that provide real-time insights and responsive oversight. We will seek to use the opportunities provided by artificial intelligence (AI) and its emerging use in regulated activities to achieve a stepped change in our use of data.
 - **Proportionate and Risk-Based Regulation:** Reviews consistently advocate for regulation that is proportionate to risk and focused on outcomes rather than process. This validates our ongoing moves towards more targeted inspection programmes and bespoke regulatory tools, while

challenging us to demonstrate clear evidence of our risk-based decision making.

- **System Integration:** The merger of NHSE with DHSC exemplifies the government's expectation that organisations work as integrated parts of a health system rather than independent entities. For the HTA, this requires strengthening our collaborative relationships and demonstrating how our regulatory activity contributes to broader health system objectives.
- **Organisational Change:** It is still to be determined if the ALB Landscape Review, the Fuller Inquiry Recommendations or any other initiative might result in minor or major organisational changes for the HTA. The HTA will respond fully to Government decisions, keeping improvements in public service delivery at the heart of any changes to structures or functions.

Strategic Alignment

14. In August 2024, the HTA published its three-year strategy (2024-27) anticipates and aligns with the reform agenda emerging from recent reviews as illustrated in the table below.

HTA Strategic Priority	Government Reform Theme	Specific Alignment Examples
Approach to Regulation	Innovation and Growth	Development of proportionate tools; regulatory sandboxes for emerging technologies
Trust and Confidence	Patient Safety Focus	Authoritative expertise; evidence-based standards that support public confidence
Use of Information	Digital Transformation	Enhanced data sharing; real-time risk intelligence; predictive regulatory insights and use of AI capacity and capability.
Efficient and Effective	Value for Money	Demonstrated efficiency savings; targeted resource deployment; outcome-focused regulation

Managing Strategic Risk in an Era of Change

15. For this year's Strategic Risk Register, the HTA has identified "failure to keep pace with innovation, growth and reform" as Strategic Risk 4, currently assessed as "at tolerance". The current analysis is based on a scenario that if the HTA fails to adapt effectively, we might risk becoming or being interpreted as a barrier to innovation rather than an enabler, potentially leading to stakeholder pressure for change. Successful adaptation, would conversely, build on our current innovations to be an authoritative voice on tissue and cell

regulation and a right-touch regulator, irrespective of whatever functional or organisational changes might ensue for the HTA.

16. Our strategic priorities provide our primary mitigation to the identified risk, but we are supplementing these with enhanced horizon scanning, regular stakeholder pulse surveys, and scenario planning exercises to test our responsiveness to different change trajectories. We regularly assess the status and scoring of this and other strategic risks.

Staying Connected

17. As well as notable changes to the overall governance of the health system, and within that the health sector ALBs, arising from the ongoing merger of NHS England with DHSC, and subsequent restructuring within the new body, a new Permanent Secretary (Samantha Jones) has recently been appointed to replace Sir Chris Wormald who has become the Cabinet Secretary. Our Chair and CEO continue to attend the regular meetings established for the health sector ALBs, which is chaired by the Permanent Secretary. Staying connected and responsive, and continuing to collaborate during functional, structural or other reforms are important aspects by which to navigate strategic change.

Next Steps

18. We are working to respond by In bringing these different reform initiatives together, determining the implications for the HTA, and developing a combined direction of travel. This runs in parallel with our established planning process to unpack our existing HTA Strategy and develop our 2026/27 Business Plan. Our planning is taking stock of existing delivery, strategic ambitions and crucially the changes required responding to the above initiatives. The main areas of focus include:
 - Responding to specific requirements for the HTA from the reform agenda
 - Maintaining authoritative expertise while developing regulatory capacity for new technologies
 - Accelerating digital transformation initiatives to demonstrate regulatory innovation and efficiencies
 - Developing the HTA's position as an exemplar of modern, innovation-enabling regulation
 - Demonstrating measurable contribution to health system objectives and economic growth
20. This planning work informs the HTA's strategic priorities for 2026/27 and

beyond. As proposals directly impacting the HTA emerge, these will be considered by the executive and presented to the Board for consideration, using our business planning cycle as the vehicle for implementation.

Recommendation

21. The Board is asked to note the report and the analysis of key strategic developments and consider the implications for the HTA.