

Human Tissue Authority Board Meeting

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An assessment of the HTA's impact

Purpose of paper

1. To share the findings of a recent assessment of the HTA's impact that also considered a counterfactual to the regulation and oversight of human tissue, cells and organs.

Decision making to date

2. The findings and report were presented to SMT in early November 2023.

Recommendation

3. The Board is asked to note the findings from the assessment and to comment on the implication of these findings for the HTA.

Background

4. Over the last three years, the HTA has adapted and flexed its operations in a landscape that is continually evolving in terms of activities, new technologies and risk.
5. The HTA remains mindful of the continued need to demonstrate relevance and credibility within the sectors that it regulates and in fulfilling its statutory duties under the Human Tissue Act 2004.

6. In order to remain responsive, the HTA has identified and adopted a range of changes to its approach in regulating human tissue, cells and organs. As the HTA looks ahead and develops its strategy for the next three years, it is essential that it: keeps pace with the changes in life sciences, maintains effectiveness as a regulator through proportionate regulation, and continues to foster the trust and confidence of our professional and public stakeholders in identifying and responding to areas of risk.
7. To assist with this, the HTA's 2023/24 Business Plan committed to undertake an "assessment of our impact". For the purposes of this assessment, impact was defined or identified as how the HTA's activities have a marked effect or influence in delivering its vision and mission, and the changes it seeks to make. For example, how monitoring and responding to developments and areas of innovation in HTA-regulated sectors can support innovation and growth in life sciences.
8. The assessment was designed to be an internal resource that could be used to assist and inform planning and resource deployment in coming years (along with other information sources and strategic developments).
9. Over the last five months, the HTA worked with Kaleidoscope Health and Care – an independent contractor – to support an independent assessment of the HTA's regulatory and business activities, and develop a better understanding of its impact. The work sought to provide an overview of the HTA's impact and to help equip the HTA with tools to carry out further or future work in relation to its impact.
10. The limited scope of the assessment means that there is an inevitable focus on activities and functions performed by the HTA. The work involved engaging with a sample group of stakeholders, including licensed establishments, arm's length bodies (ALBs) and devolved administrations. With a wider scope but bigger budget, the HTA would have liked the assessment to have been used to assess public trust and confidence in the HTA.
11. This paper seeks to share the findings and sets out the context for how they may be used to:
 - a. inform the development of the HTA's Strategy 2024-27
 - b. inform opportunities for improvement and / or ongoing commitment
 - c. evidence the impact that the HTA has against a counterfactual of no or alternative regulation of human tissue, cells and organs, and
 - d. demonstrate the HTA's impact through an annual review.

Approach

12. HTA commissioned Kaleidoscope to (a) explore the impact of the HTA by understanding its role as a regulator in the wider health system, and (b) identify the contribution and attribution between its activities and desired impact.
13. Work to assess the HTA's impact was delivered in the following three phases:

- a. Phase One: Discovery**

This phase saw the development of an evaluation framework to support an assessment of the HTA's impact. This framework is reflected in [Annex A](#) and sought to determine how impactful the HTA considers itself to be and where it would like to strengthen its position. To do this, the framework maps the HTA's activities, its tangible deliverables (referred to as 'outputs') and the impact of those deliverables – both immediately (known as 'outcomes') and in the long-term.

Developing the framework involved interviewing each member of SMT and facilitating a workshop with a number of departmental heads and managers from across the organisation for their views and insights.

- b. Phase Two: Data collection and analysis**

Qualitative and quantitative data was collected and analysed in this phase, to help Kaleidoscope identify whether the HTA is having its desired impact, as defined in paragraph 7 above. It also sought to explore the counterfactual and identify where the HTA could continue with, adapt, or improve measures and tools that it already has in place.

To do this, a data-focussed workshop was held, colleagues across the organisation were interviewed, and data collection and validation workshops took place with external stakeholders – such as licensed establishments and other ALBs.

- c. Phase Three: Reporting**

This phase saw the production of a final report that included findings and recommendations, which were informed by Phases One and Two. It also included workshops and presentations to discuss preliminary findings, and a skills transfer session to support any further and future assessments.

Summary of findings

14. Overall, the report concluded that the HTA's activities are impactful in the regulation of human tissue, cells and organs.
15. The findings identified a number of areas and activities of impact, such as:
 - a. its strong reputation as an expert regulator
 - b. its ability to maintain the trust of licensed establishments, and
 - c. its ability to facilitate collaboration.
16. The findings also identified opportunities for improvement. For example, this included using information more proactively to provide insight on sector performance, inherent risk and the pressures and challenges faced by sectors and establishments.
17. All findings were structured around the following **five key areas**:
 - **How HTA activities result in, and contribute to, achieving its intended impact:** Findings showed that there is a causal link between the HTA's work and positive impact. It also found consensus that without the HTA (or a similar body), specific positive outcomes could not be achieved, and that another regulator would need to develop the skills, relationships and ways of working to match the HTA's impact.
 - **How the HTA's performance achieves impact:** The report found that the HTA's broader impact is intended and achieved through its core functions (for example, by providing guidance, licensing and inspecting). It also found that the HTA could further balance proactive activities with core activities to achieve impact.
 - **How HTA activities deliver impact:** Findings explained that there is a gap in activity to ensure the HTA is having an impact on public confidence, and that the HTA could do more through its activities to foster its external relationships for wider impact on the health and life sciences system.
 - **How the HTA measures its impact:** The report found that the HTA's key performance indicators (KPIs) and performance indicators (PIs) could be more effective at measuring anticipated outcomes as well as tangible deliverables
 - **How impactful the HTA is in the wider health and life sciences system:** Findings showed that the HTA plays multiple roles within the wider system which each contribute to how it delivers impact. The report noted that using alternative or additional approaches to regulation could have the potential to help the HTA improve its impact.

18. There is a level of confidence and assurance to be taken from the findings, particularly in relation to the HTA's current activities and potential areas for improvement. The HTA is considering how these could be prioritised as part of its annual planning and in the delivery of its strategic vision.
19. There are a number of projects currently underway or planned that respond to and will assist the HTA in strengthening its existing impact or informing further change. Examples of these include:
 - a. progress and activities under the Communications and Engagement Strategy
 - b. work on the Review of Inspections
 - c. a review of the HTA's Strategy, and
 - d. the revision of KPIs for the 2024/25 business year.

The counterfactual

20. One critical finding is that of the counterfactual – ie, the impact on the use of human tissue, cells or organs if they were not regulated and the HTA did not exist, or if another regulator was to take on the HTA's role.
21. In the event that there was no regulation of human tissue, cells and organs, stakeholders reflected that there would be a heightened risk of unethical practices, such as unauthorised tissue retention, substandard body storage conditions and illegal body trafficking and organ harvesting. Collectively, it was thought that these harmful or exploitative activities could undermine patient safety, the dignity of the deceased, the wellbeing of patients and families, and wider public confidence.
22. The report reached a consensus that it would be challenging and would take time for another regulator to fulfil the role of the HTA. This was due to the HTA having recognisable impact that is achieved through the full scope of its core functions and regulatory tools. The technical expertise of the organisation was recognised and valued by stakeholders, alongside its strong relationships with licensed establishments and the wider health and life sciences system. As a result, the regulation of human tissue, cells and organs was not considered to be easily replicable by another body in the short term.
23. The report made clear that the HTA is a valued regulator that impacts its regulated sectors, specifically through published advice and guidance relating to standards and the Codes of Practice, and in advising licensed establishments to achieve and / or maintain compliance through ongoing engagement. Together, this confirms in headline form that there is merit and value in the ongoing regulation of human tissue, cells and organs.

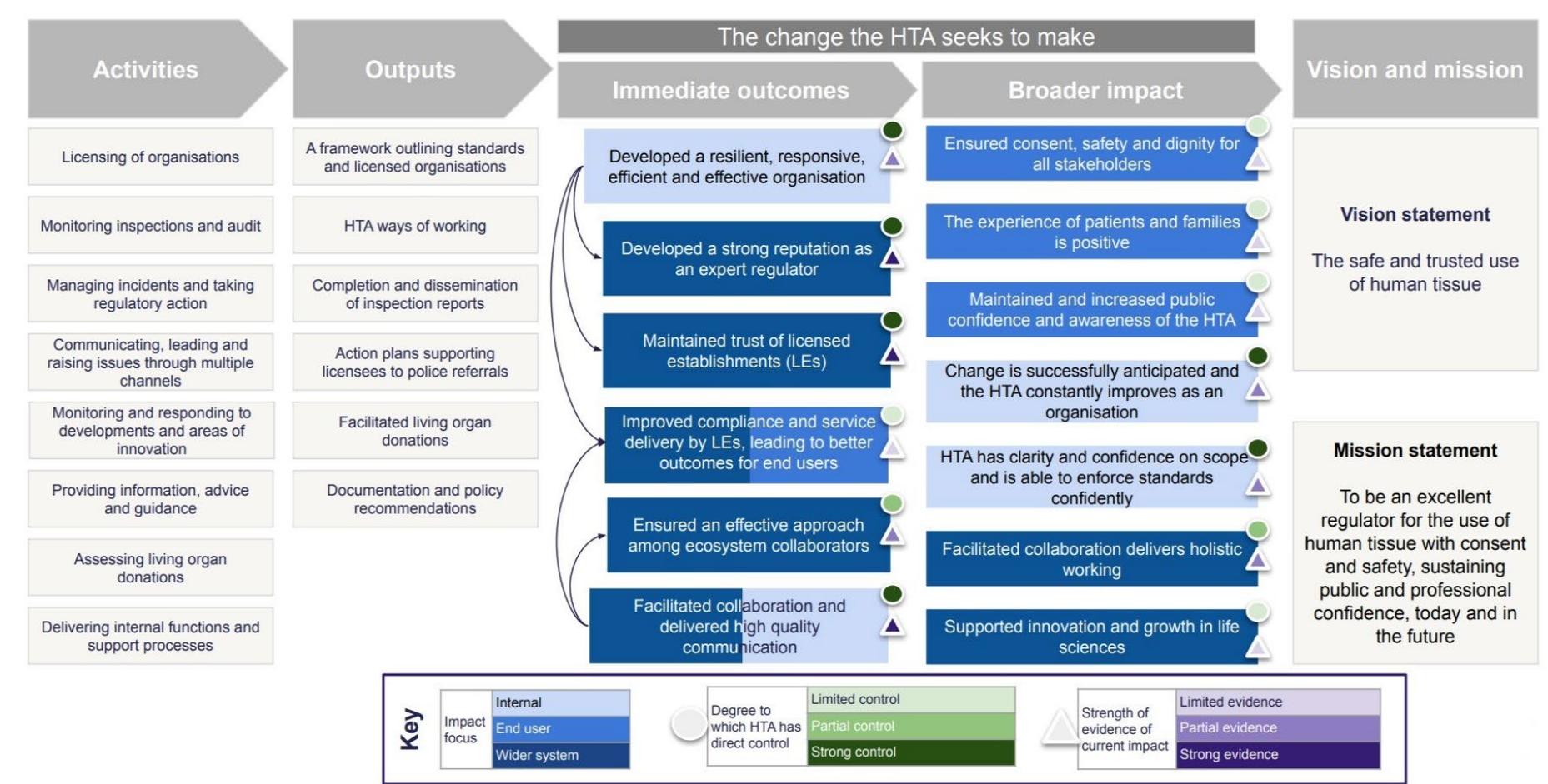
Looking forward / next steps

24. The HTA is committed to completing structured evaluations of changes to its practice and surveys to understand the impact of its activities and approach to regulation. This assessment was the first structured and detailed assessment of the HTA's impact and consideration of a counterfactual.
25. The findings provide valuable internal and external insight to the HTA's activities. The HTA will seek to use this insight to maintain, develop and potentially consider the deployment of additional investment and resources to carry out its activities, including those that stakeholders such as licensed establishments consider most helpful. The HTA is committed to ensuring that its approach to regulation remains proportionate and effective, as well as the activities and tools that it uses to fulfil its statutory purpose.
26. The HTA recognises this assessment as one source of information and intelligence that can be used to inform and align priorities in annual business planning, the HTA's strategic direction, and possible opportunities for collaborations with partner organisations in the wider life sciences system. By focussing on these areas, the HTA seeks to strengthen and improve how it delivers activities that result in, or contribute to, an immediate or long-term impact.
27. The HTA has already begun to use the findings from this work. For example, it is using its convening role to promote best practice through engagement activities and using evidence-based risk insight to strengthen advice and guidance to regulated sectors. Work is also being progressed to review and enhance inspection methodologies via a dedicated project.
28. Moving forward, the HTA will consider how it may routinely embed impact in day-to-day business-as-usual activities as well as wider opportunities. To assist with this, the HTA is in the process of sharing and communicating the findings across the organisation to promote discussion and ensure we communicate impact with a common, authoritative voice that is grounded in evidence. This will be reflected in the next HTA Strategy that is currently under development.

Recommendation

29. The Board is asked to note the findings from the assessment and provide comment on the implications of the findings for the HTA.

Annex A – Evaluation framework



HTA meeting papers are not policy documents
 Draft policies may be subject to revision following the HTA Board meeting