Human Tissue Authority

Business Plan 2025/26

Foreword

Dr Colin Sullivan, Chief Executive

Making sure human tissue, cells and organs are handled with dignity, used with the proper consent of those involved, and stored safely, is at the heart of our work at the Human Tissue Authority. That's what we'll continue to do in an environment of ongoing change and multiple technical advances. We aim to be an excellent, modern and accountable regulator dealing proportionately with the sectors we oversee today, whilst preparing for future regulatory challenges.

In recent years, the HTA sought to modernise our approach to regulation whilst delivering a comprehensive licensing and inspection programme for the establishments we regulate. In 2024/25, we set out our next three-year Strategy, challenging ourselves to regulate the sectors we oversee yet more proportionately by deploying a different selection of regulatory tools and engaging collaboratively with partners and stakeholders to work together for the public good.

We set and oversee the required standards through our regulatory approach, it is the responsibility of licensed establishments to ensure their policies, procedures and practices are compliant. If we find shortfalls in practice, we will be open and transparent in our findings and the steps we are taking to maintain the confidence of the public and professionals working in life sciences and across the broader healthcare system. The complexity of activities particularly in the research and human application sectors means we are not regulating in isolation. Collaborating with other regulators and assessment bodies helps ensure that any framework is proportionate, supports the achievement of set standards and does not hinder or stifle innovation or development.

Our Business Plan for 2025/26 represents year two of our three-year Strategy, in which we will develop the capabilities necessary to deliver on our Vision and Mission in the most innovative, effective and value for money ways possible. We have built this Business Plan around our four strategic themes; approach to regulation, trust and confidence, use of information and efficient and effective, capturing both core operations and change activities.

In this Business Plan we have included an explicit MoSCoW prioritisation in terms of strategic alignment for the various change activities that we are proposing to undertake, so that we are being realistic about which items we are able to commit to, and to enable us to manage the Business Plan in a flexible way across the year:

- Must do – firm commitments for the year
- Should do – items that we intend to be able to bring online during the year
- Could do – items that we hope to be able to bring online during the year
- Won't do – items that we have had to deprioritse (not listed).

We will continue to use active Portfolio Management as the dynamic means through which we then deliver, manage and report on our Business Plan, tracking progress through key performance indicators and successful completions of change activities. We are now publishing our key performance indicators in this document to ensure that our performance can be scrutinised.

During the year, we will:

- Maintain flexibility in resource allocation
- Respond quickly to environmental changes
- Adjust the Business Plan throughout the year if appropriate
- Make decisive decisions to start, pause, stop or change work as necessary.

In this Business Plan we have consciously moved certain work across from formal change activities to core operations where work on topics is now becoming work routine or can be undertaken in a lighter touch way. This means that we have a consciously shorter list of change activities proposed for 2025/26, so that we can focus on our big-ticket goals. We have set an ambitious agenda and will seek to deliver on it, collaborating with our partners to achieve the best possible outcomes.

For 2025/26 we are challenging ourselves to fulfil our role efficiently and effectively and we commit to working with Government to contribute savings in-year to support as best we can.

Executive Summary

The Human Tissue Authority (HTA) is an executive Non-Departmental Public Body sponsored by the Department of Health & Social Care (DHSC). Our overall goal is to maintain public confidence in the removal, storage and use of human tissue and organs and ensure that these activities are undertaken safely and ethically, and with proper consent. This plan sets out our strategic themes and the work we will do during 2025/26 to deliver them.

Our approach to regulation

During 2025/26, we will look to focus our attention on developing our regulatory practices, achieving the challenging key performance indicators that we have set including a comprehensive programme of compliance assessments. We will continue the development of a new target operating model for delivering regulation for each of the sectors we cover, seeking to be creative and innovative in developing our operations, looking to future opportunities and new ways of providing services. In 2025/26 we will focus more particularly on strengthening our approvals processes for living organ donations and will respond to any changes to legislation around Substances of Human Origin.

Building public trust and confidence

A key focus for 2025/26 will be to continue to build public trust and confidence in our ability as a regulatory body. To this end we will initiate a review of our own Codes of Practice to assure ourselves and our stakeholders that they are reflective of best practice. This topic is likely to lead to a significant programme of work across multiple years, and in 2025/26 the aim will be to complete an initial review and identify where changes are necessary.

The use of data and information

Following an upgrade to our Customer Relationship Management system in 2024/25, in 2025/26 we will implement a Change Authority Board process so that new ideas and developments can be appropriately considered and managed. We anticipate that new initiatives will be funnelled through this route and start to bear fruit in-year, but obviously we can't share those details just yet because the ideas are still very much forming. Ensuring that our technology and data is stable and robust is of critical importance to us.

Being an efficient and effective public body

Similarly, ensuring that our supporting functions are high-performing and efficient is vital for a small organisation with a big role to fulfil. We will renew our commitment to achieving corporate value for money and operating as an exemplar of public sector performance. In 2025/26 we will embark on two major change initiatives in terms of our support services. We intend to replace our Finance System with a solution with better functionality and will look to focus our corporate mind on implementing our new People Strategy to ensure that we are supporting and rewarding our colleagues.

Introduction

Our Vision

The safe and trusted use of human tissue. (We will help achieve this through delivering on our Mission.)

Our Mission

To be an **excellent regulator** for the use of human tissue with **consent and safety**, sustaining public and professional **confidence**, today and in the future.

How we work

- We license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act (2004)
- We license organisations that carry out a range of activities associated with the use of human tissues and cells for patient treatment, as required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)
- We license organisations undertaking organ transplants as required by the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended)
- We monitor and inspect or audit organisations to ensure they comply with the requirements of the legislation and our Codes of Practice
- We use our powers to take regulatory action where we identify non-compliance
- We assess living organ donations to ensure donors are protected from duress or coercion, and that no reward is offered or given
- We provide information, advice and guidance to the public and professionals about the nature and purpose of activities within our remit
- We monitor developments relating to activities within our remit and advise Government on related issues
- We work collaboratively with partners across the system
- We actively engage with our stakeholders
- We are open and transparent in our publications to maintain public confidence
- We are proportionate in our approach to our work.

In addition to our statutory role, we are increasingly called upon to provide advice on areas related to, but not specified in, legislation. This is especially important in areas of emerging technology and research not originally envisaged when the Human Tissue Act was enacted.

Our remit under the Human Tissue Act (2004) covers England, Wales and Northern Ireland and under other human tissue legislation includes England, Wales, Northern Ireland and Scotland[1]. We license over 800 premises across 6 sectors and publish standards and requirements that those working within these regulated fields must meet.

Whilst the HTA has a statutory duty to superintend compliance and an influential role in promoting good practice, public confidence in the use of human tissue cannot be safeguarded by the HTA

[1] When we refer to human tissue legislation, we mean human tissue legislation that is within the HTA's remit. This currently includes (but may not be limited to in the future):

a) The Human Tissue Act 2004 ("the Act")
b) The Human Transplantation (Wales) Act 2013
c) The Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) ("the 2007 Regulations")
d) The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended) ("the 2012 Regulations")
e) Additionally, the Scottish Government has delegated certain functions to the HTA under The Human Tissue (Scotland) Act 2006.

alone. Public confidence is also dependent on the individuals and organisations that undertake activities within the HTA's remit acting within the standards and requirements of the legislation.

Our values

Our Strategic Approach

Our strategic approach is based on being clear about the risks we are regulating, and then being proportionate and targeted in response. In 2023/24 we concluded our last three-year Strategy and developed our next, which in which we are focusing on the following four strategic themes. As we begin year two of the current three-year period, we will be bold and ambitious as we focus on efficient delivery whilst striving to develop and innovate even further.

Approach to regulation

Delivery – core operations for 2025/26 with Key Performance Indicators
Regulation – fulfilling our licensing, inspection, incident management and approvals functions, providing technical advice and superintending compliance across the sector, including responding to the Fuller Independent inquiry and engaging with a review of our implementation of the Duty to Report[2] Regulations *Key performance indicators:* • *222 compliance assessments across all sectors [reported quarterly against planned allocation]* • *Decisions reached on 70% of new licence applications within 90 days of the application fee being paid (rolling annual average) [reported quarterly]* • *99% of panel and non-panel cases actioned within 10 and 5 working days respectively [reported monthly]*
Development – proposed change activities for 2025/26 with MoSCoW (must do, should do, could do, won't do) prioritisation
Innovation in inspection; develop and implement changes to our regulatory activities to bring about efficiencies, supporting evidence-based assurance practices and enhanced compliance processes (Year 3) *[Must do]*
Further strengthen our processes for living organ donation approvals *[Must do]*
Respond to potential changes to Substances of Human Origin Legislation *[Must do]*

[2] The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024

Trust and confidence

Delivery – core operations for 2025/26 with Key Performance Indicators
Communications – informing stakeholders, promoting our Mission, and showcasing our positive impact, using a mix of channels to effectively reach our target audiences, and developing a relationship management model
Policy and Development – implementing and overseeing changes to relevant legislation and regulatory tools to ensure the HTA and its regulated sectors are compliant with laws; supporting the Department of Health and Social Care and others by providing advice and guidance on legislative matters relating to human tissue, and publishing a review of the last business year
Development – proposed change activities for 2025/26 with MoSCoW (must do, should do, could do, won't do) prioritisation
Initiate a review of our Codes of Practice to ensure that they are reflective of best practice; year 1 (25/26) will be focused on establishing a review process, completing an initial review and identification of changes if required *[Should do]*

Use of information

Delivery – core operations for 2025/26 with Key Performance Indicators
Information Technology – stable technology operations focusing on user experience and engagement *Key performance indicator:* • *99% system availability across our core essential functions, outside of scheduled maintenance routines and system patching [reported monthly]*
Data – production and analysis of rich data and records to inform both our strategic direction and operational capabilities (including Cyber Assessment Framework, Records Management and information governance), and embedding our Regulatory Insight Model and Index *Key performance indicator:* • *Bi-annual open datasets are assessed, validated and published within 10 weeks of quarter end [reported annually]*
Development – proposed change activities for 2025/26 with MoSCoW (must do, should do, could do, won't do) prioritisation
Implement CAB (Change Authority Board) process within Information Technology so that system requests can be appropriately considered and managed (either through core operations or change activities, as required, on a case-by-case basis) *[Could do]*

Efficient and effective

Delivery – core operations for 2025/26 with Key Performance Indicators
Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including Risk Management and seeking opportunities for Arm's Length Body collaboration)
Portfolio Management – producing the Business Plans and supporting and monitoring delivery against them through the Portfolio approach
Private Office – facilitating Board, Committee, and Senior Management functions, providing good governance support and compliance with Government requirements
Corporate Services – coordination of support services including governance quality management, compliance with Government standards for operations, critical incident response planning, corporate correspondence, Freedom of Information Act requests, and event management *Key performance indicators:* • *90% of enquiries answered within 10 working days [reported monthly]* • *100% of FOIs (Freedom of Information requests) responded to within 20 working days [reported quarterly]*
Finance – stable financial operations (where applicable through shared services to achieve value for money) with balanced budgets and unqualified accounts *Key performance indicators:* • *Actual spend within 3% of budget [reported quarterly]* • *Debt no more than 5% of income at year end [reported annually]*

Audit and Risk – coordination of appropriate organisation controls to facilitate scrutiny and oversight by our stakeholders

Key performance indicator:

- *Unqualified external audit opinion received [reported annually]*

Health and Safety – processes and procedures to prevent accident or injury at work

Key performance indicator:

- *100% of 'reportable incidents' reported to HSE (Health and Safety Executive) within 10 working days [reported quarterly]*

Human Resources – stable people operations (through a shared service model to achieve greater resilience) with support and guidance for our colleagues

Key performance indicators:

- *Staff sickness no more than 3% [reported monthly]*
- *Attrition rate excluding planned exits (Fixed Term Contracts) no more than 18% [reported monthly]*
- *Total attrition rate no more than 20% [reported monthly]*

Development – proposed change activities for 2025/26 with MoSCoW (must do, should do, could do, won't do) prioritisation

Replace our current Finance System with an updated solution that includes 'procure to pay' and expenses functionality *[Could do]*

Implement our People Strategy that sets the direction for our organisational development *[Should do]*

Finances

The HTA receives funding from two main sources. The majority (over 80%) comes from licence fees, with the remainder provided as grant-in-aid from our sponsor, DHSC. We also receive a small amount of income for undertaking activities on behalf of the Devolved Administrations.

The licence fee income pays for a range of activities associated with our licensed establishments:

- Evaluating licence applications
- Making licensing decisions and issuing licences
- Processing variations to licences
- Conducting site visits and following-up shortfalls
- Taking regulatory action
- Providing advice and guidance to licensed establishments
- The on-costs of operating our organisation.

Grant-in-aid funds our role in assessing living organ donations and bone marrow / peripheral blood stem cell donation cases and a proportion of our overheads that are not directly associated with our work with licensed establishments.

We place great importance on ensuring that our finances are managed efficiently, effectively and in a way that minimises risk.

As an Arm's Length Body, we continue to monitor developments in the wider public sector financial environment and are committed to implementing best practice. We have robust financial procedures and policies in place and strict controls in relation to authorisation of expenditure.

The high-level budget for 2025/26 is shown below:

	BUDGETS	
	2024/25	**2025/26**
EXPENDITURE		
TOTAL STAFF COSTS	4,742,720	5,034,465
TOTAL OTHER COSTS	219,000	193,120
TOTAL CORPORATE SHARED SERVICE COSTS	1,033,314	1,205,469
TOTAL EXPENDITURE	**5,995,034**	**6,433,054**
INCOME		
TOTAL CENTRAL FUNDING	753,913	475,334
TOTAL LICENCE FEES	5,189,239	5,898,098
TOTAL OTHER INCOME	51,882	59,622
TOTAL INCOME	**5,995,034**	**6,433,054**

Capital

Our capital investment plans for 2025/26 support the implementation of our Digital and IT Strategy. We will limit our expenditure to our normal delegation of Capital Funds from DHSC once confirmed.

Efficiency and productivity

We remain committed to seeking benefits from continuous improvement initiatives and delivering value for money for both the public and the establishments we licence. Following many years of making efficiencies, we are a very lean organisation. We remain committed to delivering our core functions to a high standard, continuing to be efficient and effective in the way we work, and being mindful of the importance of focusing on those outcomes that really matter to the public and professionals.

Shared services

Having moved to office premises in Stratford, we are co-located with 4 other Health Sector regulators and have outsourced our Human Resources service. We are seeking to explore further potential for sharing services with these bodies to improve organisational and operational resilience.

Monitoring and performance

We operate a comprehensive Portfolio Management approach to Business Planning and Performance Management, linked to the best-practice Management of Portfolios syllabus. This has allowed us to re-evaluate our performance measures to ensure that we can transparently demonstrate our delivery against stated objectives and plans. We account for our performance on a quarterly basis to the Board and to DHSC. The information we use to demonstrate our performance can be found in the “Authority Meetings” section of our website.