

Foreword by 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 2022/23 and 2023/24, 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 are aiming to build on those foundations with our next three-year Strategy, being bolder and continuing to challenge 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 effectively together for the public good.

Whilst 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 2024/25 represents year one of our new three-year Strategy, in which we will build the foundations 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 new 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 (must do, should do, could do, won't do) prioritisation for the various change activities that we are proposing to undertake, so that we are being realistic about which items we are committing to, and to enable us to manage the Business Plan in a dynamic way across the year. We will continue 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 have set an ambitious agenda and seek to deliver on it, collaborating with our partners to achieve the best possible outcomes.

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 2024/25 to deliver them.

Our approach to regulation

During 2024/25, we will look to continue the important work started in 2022/23 and 2023/24 to change and develop our regulatory practices. Building on this work, we will continue the development of a new target operating model for delivering regulation for each of the sectors we cover. We will seek to be creative and innovative in developing our operations, looking to future opportunities and new ways of providing services.

In 2024/25 we will focus more intently on technology and the use of data to improve our risk assessment and operational delivery, digitising wherever possible. We will also work closely with the DHSC to implement the new 'duty to report' as comprehensively and effectively as possible.

Building public trust and confidence

A key focus for 2024/25 will be to continue to build public trust and confidence in our ability as a regulatory body. We look forward to engaging with the Government's Public Bodies review programme (as and when we are notified) and working collaboratively across the sector with partners and stakeholders to deliver public protection and confidence in the use of human tissue.

The use of data and information

In 2024/25, we will aim to further develop our data and analytical work, seeking to ensure that we are keeping pace with the digital world that we operate in. We will start redeveloping our CRM system, develop our regulatory insight to make better use of available data to improve our operational practices and decisions, and will continue to provide datasets on an open-source basis to drive compliance and public protection through transparency.

Being an efficient and effective public body

2024/25 represents an important year for the HTA, strategically, as we begin our new three-year strategy. As an organisation we are looking to be ambitious and challenge ourselves to achieve greater efficiency and effectiveness. To this end, we will be continuing to pursue shared services opportunities where practicable, improving our systems and processes, and thinking about how we reward and retain the best talent, to assist us in fulfilling our Vision and Mission and delivering the functions entrusted to us.

Our Vision

The safe and trusted use of human tissue.

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.

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 Scotland¹. 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 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

Following the setting of our revised Vision and Mission, last year we refreshed our values for the important and ambitious role that we play as we seek to be more inclusive and further improve performance. The way that we are now expressing our organisational values is through; Collaboration, Openness, Respect and Excellence.

HTA CORE VALUES



COLLABORATION



OPENNESS



RESPECT



EXCELLENCE

1. 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.

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 will focus on the following four strategic themes. As we begin the next 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**

**Trust and
Confidence**

**Use of
Information**

**Efficient and
Effective**

Proposed activities

Approach to Regulation

Delivery – core operations

Regulation – fulfilling our licensing, inspection, incident management and approvals functions, providing technical advice and superintending compliance across the sector:

- Ambitious programme of inspection and other regulatory assessments across our regulated sectors
- Undertaking assessments of new licence applications
- Providing accurate and fit-for-purpose technical advice and guidance to a wide range of stakeholders, including the public
- Responding to reported incidents
- Fulfilling all statutory obligations relating to Living Organ and Bone Marrow donation
- Decision-making and action for identified shortfalls and reported incidents

Development – proposed change activities for 24/25 with MoSCoW (must do, should do, could do, won't do) prioritisation

Continue to support and respond to the Fuller Independent Inquiry, identify and deliver workstreams:

- In response to Phase 1,
- Emerging themes from Phase 2, and
- To take forward HTA priorities for developing our approach to regulation in the Post Mortem sector and more widely [*must do*]

Innovation in inspection; develop and implement changes to regulatory activities to support evidence-based assurance practices and enhanced compliance processes; initial piloting within the Post Mortem sector [*should do*]

Items that we have had to consciously deprioritise as *won't do*² for 24/25 include; further strengthening our process for approving Living Organ Donations and developing a Compliance and Enforcement strategy and associated policies

² Whilst 'won't do' items won't be actively prioritised, we may need to undertake some preparatory work on these items and / or bring them online in-year as circumstances develop

Trust and Confidence

Delivery – core operations

Communications – undertaking a proactive and responsive cycle of work seeking to facilitate flows of critical information and engagement across stakeholders, including events, website, social media, and wider advice and guidance

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

Development – proposed change activities for 24/25 with MoSCoW (must do, should do, could do, won't do) prioritisation

Engage with Government's Public Bodies review programme, demonstrating our value, impact and the provision of positive outcomes for the public, as and when this review occurs [*must do** if notified*]

Facilitate an in-person event to draw together stakeholders and improve relationships and share best practice [*must do*]

Update the HTA's approach to horizon scanning and establish an Insight Network to identify and discuss emerging developments and innovation [*could do*]

Publish a 2023/24 review of the HTA's activity over the last business year and its impact [*must do*]

Items that we have had to consciously deprioritise as *won't do*³ for 24/25 include; undertaking a fundamental review of our Codes of Practice to ensure that they are reflective of best practice (building on the factual accuracy processes recently completed)

³ Whilst 'won't do' items won't be actively prioritised, we may need to undertake some preparatory work on these items and / or bring them online in-year as circumstances develop

Use of Information

Delivery – core operations

Information Technology – stable technology operations (exploring alternative service possibilities to achieve greater resilience) with appropriate tools and support

Data – production and analysis of rich data and records to inform both our strategic direction and operational capabilities (including DSPT, records management and information governance)

Development – proposed change activities for 24/25 with MoSCoW (must do, should do, could do, won't do) prioritisation

Review and finalise our Data and Technology strategy that sets the direction for future innovations across all our work *[must do]*

Complete backlog updates to CRM such that it is fit-for-purpose (Phase 2) *[must do]*

Develop our Regulatory Insight Model and Index (RIMI) to increase our systematic use of data as a driver for our regulatory practices and decisions *[must do]*

Review our records management arrangements to maximise our effectiveness *[should do]*

Items that we have had to consciously deprioritise as *won't do*⁴ for 24/25 include; exploring the possibility of CRM licensing changes to enable more accurate recording of licensable activities at hub / satellite sites, and automating data and records management systems

⁴ Whilst 'won't do' items won't be actively prioritised, we may need to undertake some preparatory work on these items and / or bring them online in-year as circumstances develop

Efficient and Effective

Delivery – core operations

Senior Management Team – strategic direction and leadership of operational delivery across the organisation (including risk management and seeking opportunities for ALB 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

Finance – stable financial operations (where applicable through shared services to achieve value for money) with balanced budgets and unqualified accounts

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

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

Development – proposed change activities for 24/25 with MoSCoW (must do, should do, could do, won't do) prioritisation

Replace our current finance system with an updated solution (that covers HFEA too) that includes 'procure to pay' and expenses functionality [*should do*]

Finalise the outsource of Human Resources on a shared services model, such that we are better able to innovate [*must do*]

Develop a People strategy that sets the direction for our organisational development and builds on the values and behaviours work from 23/24 [*must do*]

Items that we have had to consciously deprioritise as *won't do*⁵ for 24/25 include; sourcing and implement a digital Board pack software so that our meeting cycles become more efficient, and reviewing our pay and grading, implementing changes as appropriate

⁵ Whilst 'won't do' items won't be actively prioritised, we may need to undertake some preparatory work on these items and / or bring them online in-year as circumstances develop

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 2024/25 is shown below:

BUDGETS

	2023/24	2024/25
EXPENDITURE		
TOTAL STAFF COSTS	4,255,675	4,742,720
TOTAL OTHER COSTS	170,500	219,000
TOTAL CORPORATE SHARED SERVICE COSTS	1,109,806	1,033,314
TOTAL EXPENDITURE	5,535,981	5,995,034
INCOME		
TOTAL CENTRAL FUNDING	1,003,243	753,913
TOTAL LICENCE FEES	4,481,231	5,189,239
TOTAL OTHER INCOME	51,507	51,882
TOTAL INCOME	5,535,981	5,995,034

Capital

Our capital investment plans for 2024/25 are based on our cyclical refresh of equipment. As a result, 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, finding further efficiencies in the way we work, where possible, and to the importance of focusing on outcomes that really matter to the public and professionals.

Shared services

We continue to operate our financial resources function as part of a shared service and have recently outsourced our human resources service. Having moved to office premises in Stratford, we are co-located with 4 other Health Sector regulators. We are seeking to explore further potential for sharing services with these bodies to improve organisational and operational resilience.

Monitoring and measuring performance

We operate a Portfolio Management approach to business planning and performance management. 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.