



Business Plan

2018 – 2019

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Introduction from the Chief Executive



During 2017, the HTA undertook a fundamental review of its strategy. This exercise gave us considerable reassurance that the public and professionals think we are on the right track with our regulatory approach. As a result, the fundamentals of our regulatory approach, which have served the public and our licensed establishments well, will remain unchanged. At the same time, the review also identified a number of emerging issues that we need to address in addition to our core regulatory business.

Specifically, we continue to see novel uses of human tissue and the emergence of new business models that bring regulatory challenges and require new ways of thinking. As a result, we are increasingly called upon to give advice and guidance on issues that are beyond our formal regulatory remit, but which nevertheless require us to provide a leadership role to ensure that public confidence is maintained.

In addition, we wish to make an active and positive contribution to national policy developments. Over the next year, we would expect to work closely with the Department of Health and Social Care to help shape the proposals to introduce opt-out consent for organ donation in England. We will also have a part to play in the delivery of the Life Sciences Industrial Strategy and in preparations for the UK's exit from the European Union. In both of these areas our expertise and history of effective collaboration will support the development of appropriate, risk-based approaches to regulation, which

balance public confidence and patient safety with building a prosperous UK economy.

These challenges will require us to operate in a more sustainable way by 2021, building in greater resilience and agility in the face of greater complexity and uncertainty in our external environment. These concepts are described in detail within this Business Plan.

We will over the next three years, need to effect significant changes to our operating model, which will involve:

- Moving towards a workforce that increasingly works remotely by design, allowing us to increase the geographic pool from which we recruit and producing savings on our accommodation costs that could be reinvested to address emerging business needs.
- Making better use of data to make the right regulatory interventions with the right establishments at the right time.
- Designing business processes and business technology in a way that best supports this new way of working.

This new operating model will require a renewed focus on high quality leadership, management and staff development to ensure a cohesive organisational culture focussed on the continued delivery of excellent regulation that protects public and professional confidence.

This Business Plan describes what we will do during 2018/19 to ensure that we continue to build our reputation as a highly effective regulator, and the building blocks we intend to put in place as we embark upon our organisational transformation.

I look forward to continuing a productive working relationship between the HTA and our stakeholders to ensure that the public's confidence in the removal, storage and use of human organs, tissues and cells is maintained.

A handwritten signature in black ink, appearing to read 'Allan', written in a cursive style.

Allan Marriott-Smith
Chief Executive

About the HTA

Our overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent.

Who we are and what we do

The HTA is an executive Non-Departmental Public Body sponsored by the Department of Health and Social Care, established by the Human Tissue Act 2004.

Our overall goal is to maintain public confidence by ensuring that the removal, storage and use of human tissue and organs are undertaken safely and ethically, and with proper consent.

We also have a role in maintaining professional confidence; by assuring that human material being used by professionals has been obtained with the proper consent and is managed with appropriate care.

Our role

- We license organisations that remove, store and use human tissue for certain activities under the Human Tissue Act 2004;
- We license organisations involved in preparing tissues and cells for use in patient treatment as required by the EU Tissues and Cells Directives;
- We license organisations involved in organ donation and transplantation as required by the EU Organ Donation Directive;
- We monitor and inspect or audit organisations to ensure they comply our standards;
- 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, our legislation. This is particularly important in areas of emerging technology and cutting-edge research not originally envisaged when the Human Tissue Act was enacted.

Our remit under the Human Tissue Act 2004 extends to England, Wales and Northern Ireland; however, we also carry out some activities in relation to the approval of living organ donations on behalf of the Scottish Government. Our remit as the Competent Authority for the quality and safety of tissues, cells and organs used in transplantation extends to the whole of the UK.

We license approximately 860 premises across the six sectors that we regulate and publish standards and requirements that those working within the regulated fields must meet.

Whilst the HTA has an influential role in superintending compliance and 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.

In line with Government requirements, we produce this document annually. It should be read in conjunction with the HTA's Strategy for 2018 – 2021, which outlines the HTA's strategic approach and high-level objectives for the three years beginning 1 April 2018.

The Authority

The HTA's non-executive board is made up of: a chair and nine Members who are appointed by the Secretary of State for Health and Social Care; one Member appointed by the Welsh Cabinet Secretary for Health and Social Services, and one by the Minister for Health in Northern Ireland. The professional Members of our board come from medical and scientific backgrounds linked to our work, and the lay Members bring a wide range of business, commercial and public sector experience.

The board's primary role is to ensure that the HTA discharges its statutory responsibilities effectively. It achieves this by setting the HTA's strategic direction and providing both support and challenge to our Executive team, which is responsible for the delivery of these responsibilities on a day-to-day basis. Further details on our staff can be found in the Resources section of this business plan.

Guiding principles

Four guiding principles continue to drive our work and underpin our regulatory framework. They should be followed in dealing with human bodies, tissue and organs:

Consent

and the wishes of the donor (or in some cases, their nominated representatives or relatives) are the primary consideration when removing, storing and using human tissue.

Dignity

is paramount in the treatment of human bodies and tissue.

Quality

must underpin the management of human bodies and tissue.

Honesty and openness

are the foundation of communications in matters pertaining to the use of human tissue and bodies.

Key activities

In our previous strategy, we described our key activities as grouped within three themes:

Delivery

how we achieve our strategic objectives today

Development

how we will improve in the future

Deployment

how we effectively use our people and resources

New strategic approach

An assessment of the evidence provides us with great reassurance that both the public and professionals think we are on the right track with our regulatory approach.

Our strategy was developed following a fundamental evaluation of the extent to which our current strategic approach protects public and professional confidence in the proper use, and quality and safety, of human tissues, cells and organs. An assessment of the evidence provided us with great reassurance that both the public and professionals think we are on the right track with our regulatory approach. However, the review identified a number of opportunities and challenges relating to our future operating environment that will require us to adapt as an organisation.

In our Strategy 2018 – 21 we set out our vision to be operating in a more sustainable way by 2021, building in greater resilience and agility in the face of increasing complexity and uncertainty in our external environment.

Sustainability

By sustainable, we mean taking a new approach to recruiting and retaining high quality staff and working in new ways to reduce the growing pressures on the staff we have.

Resilience

By resilience, we mean adapting our operating model to retain staff for longer and develop strategic alliances with other organisations to put us in a better position to manage unexpected demands.

Agility

By agility, we mean providing a highly responsive regulatory framework that supports innovative uses of organs, tissues and cells, burnishes our reputation as an expert regulator and actively supports the Industrial Strategy for Life Sciences.

We will phase the envisaged organisational transformation over the next three years. The first step in implementing the strategy will be to develop a more detailed blueprint proposal, which will outline the changes we need to make to our People Strategy, Business Technology and Estates plans.

Year 1 of this strategy represents a transition between the previous 3-year strategy and the new priorities. This 2018/19 Business Plan will therefore reflect the trade-offs between current and emerging business needs.

In order to meet the challenges ahead we require a fresh focus on our:



People

Recognising our staff as our key asset, widening the pool of candidates for recruitment and investing in training and development;



Business Technology

Ensuring our systems are not reliant on location and making strategic choices about key business systems;



Information and data

Meeting our obligations relating to data security and using information and data as a key strategic resource.

Our priorities

This business plan sets out our ambitions for 2018/19. The HTA operates a continuous business planning process - we maintain a pipeline of proposed business activities over a three-year period, which allows us to adapt and plan in response to changes in our operating environment.

Our overarching aim remains to protect public and professional confidence in the safe and proper use of human tissue – we do this by utilising a combination of regulatory tools, which we deploy according to risk across each of the sectors we regulate. Our core delivery activities are centred around licensing, inspection, incident reporting, assessment of living organ donation, providing advice and guidance, and communicating and engaging with stakeholders.

We have a long established culture of working with establishments to ensure that they meet our standards, targeting our resources at

the areas of greatest risk to patient safety and public confidence. We encourage improvement through provision of high quality advice and guidance and sharing best practice, publishing our inspection reports so we are transparent about our findings, and so that others can learn. When things go wrong we ensure that establishments take appropriate action, including measures to prevent future incidents from happening.

Whilst we have an influential role in supporting establishments to improve, we recognise that public confidence cannot be safeguarded by the HTA alone. It is also dependent on the individuals and organisations working with human tissue to act in accordance with the law and the wider regulatory framework.

We therefore continue to engage and work in partnership with the sectors we regulate.

When things go wrong we ensure that establishments take appropriate action, including measures to prevent future incidents from happening.



Our priorities

We understand that we do not regulate in a vacuum, and that it is important that we work jointly with other regulators and bodies

Implementation of our new standards

We will continue to work with establishments to fully embed our new Codes of Practice and Standards. In 2018/19 we will feedback to establishments to share the learning we have gained from regulating to the new standards, and the outcomes of the 2017/18 compliance updates.

Joint working

We understand that we do not regulate in a vacuum, and that it is important that we work jointly with other regulators and bodies to provide clarity on regulatory requirements, reduce burden where appropriate and share information to inform our regulatory approach. Over this business year we will continue to review existing relationships to ensure they deliver operationally, identify where our expert knowledge could add value in new partnerships and seek to reduce burden where we can achieve assurance from other sources.

Human Application

We continue to see the development of new products, preparation methodologies and therapeutic applications of human tissue, which increasingly require us to take an agile approach to our regulation. We work closely with other health regulators, both bilaterally and through the Regulatory Advice Service for Regenerative Medicine (RASRM), to provide clarity on the regulation of borderline products and those that span multiple regulatory remits and respond to emerging issues.

With the Regulations to transpose the EU Directives on Import and Coding coming into force on 1 April 2018, we will continue to work closely with establishments to fully implement and embed the requirements as we begin to inspect against them.

Last year we undertook an evaluation of risk in the human application sector; this year we will look to strengthen our arrangements for oversight of licensable activities carried out by third parties and improve our risk-based approach to inspection.

Organ Donation and Transplantation

In October 2017, the Prime Minister announced her intention to introduce a system of 'opt-out' for organ donation. We look forward to the Government's response to the recent public consultation, and will continue to work closely with colleagues at DHSC to ensure that public and professional confidence remain paramount considerations as any new system develops.

In 2018/19 we will also look at ways we can develop and further support our network of Independent and Accredited Assessors, as we seek to build sustainability across our systems.

Our Transplantation Advisory Group will continue to play a key role in shaping our regulatory approach, as will our relationships with stakeholders such as NHSBT and the British Transplantation Society.

Research

Our collaborative work with the Health Research Authority (HRA) continues, with HTA input into training events and the HRA's e-learning module on 'research using human tissue'. In 2018/19 we will also build on the outcomes of the joint HRA/Human Tissue Authority (HTA) public dialogue project on sharing patient data with tissue for research, to inform our regulatory approach in the sector. Both organisations continue to benefit from a secondment arrangement, which allows direct input into a number of HRA strands of work.

Post Mortem

We have strong and constructive links with a range of professional stakeholder groups, including the Royal College of Pathologists, the Association of Anatomical Pathology Technicians, the Coroner's Society of England and Wales and the Home Office Forensic Science Regulation Unit. We engage with these bodies formally through our Histopathology Working Group, and through other joint working initiatives including HTA input into training and events.

We will also continue to explore opportunities for collaboration with the United Kingdom Accreditation Service (UKAS), where there is potential to reduce burden for our licensed establishments.

Anatomy

We continue to have a good working relationship with establishments and representative bodies, including the Anatomy Associations Advisory Committee (AAAC), who are proactive in highlighting emerging issues in the sector. The HTA also frequently attend and present at sector related meetings.

We have recently seen an increase in public interest in issues relating to body donation. We receive a large number of calls on this topic and continue to provide advice and guidance to members of the public, including directing them to their nearest medical school.

Public Display

This is our smallest sector, and considered to be one of the lowest risk, particularly for static collections. This makes it important that we work with our stakeholders to ensure that our regulation remains proportionate. We have increased our engagement with establishments in this sector through our licensed establishment engagement programme and Stakeholder and Fees Group, and will continue to look for ways that we can develop our regulatory approach to ensure that burden is minimised.

Professional and public engagement

We recognise the importance of engaging with both professionals and the public on our work. We will continue with our programme aimed at improving our engagement with Designated Individuals and licensed establishments, including regular meetings with a panel of representatives to receive feedback, share learning from our work, develop our digital engagement channels and scope training opportunities.

Our website remains the primary channel through which we provide access to HTA related guidance and information. We will use the results of our recent website and digital communications surveys to inform a review of the content we publish and ensure it continues to meet users' needs.

Following the public evaluation in 2017/18, and the development of the HTA's Public Panel, the focus for the next business year will build on the insight we have gained from this work. We will continue to work closely with members of the public who are interested in our work, and seek to further develop and strengthen our relationships with other public facing and representative bodies. This will include consideration of how we can use digital channels for engagement, as well as ensuring that our key information for the public - such as our Public Guides to the Codes and our Code A: Guiding principles and the fundamental principle of consent – are accessible both on and offline, when and where they need it.

Exit from the European Union

Many of the sectors we regulate have the potential to be affected by the UK's withdrawal from the European Union. In particular, as Competent Authority for two sets of EU Directives, we recognise the importance of our role in advising Government and contributing to plans for a range of outcomes as the negotiations proceed.

Along with colleagues at the Department of Health and Social Care, we are fully committed to continuing the close working relationship with our European partners, in the interests of public health and safety.

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Our objectives and how we deliver them

The HTA's high-level aims, objectives and key milestones and deliverables for 2018/19 are set out in this section. This information is supported by our key performance indicators

(KPIs) and performance indicators (PIs), which set out how we will measure whether we are achieving those aims.

Delivery

To deliver the right mix of operational activity to maintain public and professional confidence.

Delivery objectives

Our delivery objectives are:

- Deliver a right touch program of licensing, inspection and incident reporting, targeting our resources where there is most risk to public confidence and patient safety;
- Deliver effective regulation of living donation;
- Provide high quality advice and guidance in a timely way to support professionals, Government and the public in matters within our remit;
- Be consistent and transparent in our decision-making and regulatory action, supporting those licence holders who are committed to achieving high quality and dealing firmly and fairly with those who do not comply with our standards;
- Inform and involve people with a professional or personal interest in the areas we regulate in matters that are important to them and influence them in matters that are important to us;
- Maintain our strategic relationships with other regulators operating in the health sector.

During 2018/19, we will:

- Use our knowledge of risk in each sector to drive the delivery of the right mix of regulatory tools to support and superintend compliance;
- Undertake a risk based program of site visits which provide assurance that standards are being maintained;
- Publish exception-based reports of inspections in the interests of transparency and to share learning;
- Take a proportionate and risk-based approach to non-compliance, and ensure there where there are shortfalls against standards, these are rectified within agreed timescales;
- Ensure that decisions on living organ donation cases meet agreed service standards in a way that provides the necessary protections;
- Engage with, and involve, public, Government and professional stakeholders in our work using a wide variety of channels;
- Provide high quality and timely responses to enquiries from professionals, the public and the media.

Development

Development objectives

Our development objectives are:

- Use our data and information to provide real-time analysis, giving us a more responsive, sharper focus for our regulatory work and allowing us to target our resources effectively;
- Make continuous improvements to our systems and processes to minimise waste or duplicated effort, or address areas of risk;
- Provide an agile response to innovation and change in the sectors we regulate, making it clear how to comply with new and existing regulatory requirements;
- Develop a blueprint for a future operating model, which builds our agility, resilience and sustainability as an organisation.

During 2018/19, we will:

- Look at ways we can adapt our regulatory approach based on our evaluation of risk across the human application sector;
- Implement measures to improve the sustainability of the Independent Assessor framework in living organ donation;
- Continue to work with establishments to ensure as smooth a transition as possible in implementing the EU Coding and Import Directives;
- Continue to develop our approach to engaging with licensed establishments as a key tool in ensuring compliance, in particular:
 - Launch the alpha testing version of an online platform for those at licensed establishments to engage and support each other;
 - Explore options for providing training for those at licensed establishments.
- Develop tools to improve how we prioritise and plan our regulatory activities and manage our resources, including more effective use of information and data;
- Continue to upgrade and develop our core business systems, website and online portal to better meet our business needs and the needs of our stakeholders;
- Use our unique position to advise and respond to Government in matters relating to our remit, in particular in relation to planning for EU Exit and implementing a system of opt-out for organ donation;
- Develop our People and ICT strategies as the first step in planning our organisational transformation programme, including:
 - Development of more formal arrangements for greater use of home working to support our recruitment strategy;
 - Produce an options appraisal for different models of working as an organisation, which puts our staff at the heart of what we do;
 - Improve our video conferencing, online meeting and collaboration capabilities;
 - Plan and prioritise the necessary business technology changes to support continued high quality delivery of our functions.

To make the right investment to continuously improve delivery.

Deployment

To make the right investment to continuously improve delivery.

Deployment objectives

Our Deployment objectives are:

- Manage and develop our people in line with the HTA's People Strategy
- Ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money
- Provide a suitable working environment and effective business technology, with due regard for data protection and information security
- Plan and prioritise our resources to carefully balance activity across the organisation

In 2018/19, we will:

- Act on the feedback provided by our staff survey to address key issues;
- Remodel our induction and training programme;
- Consider the introduction of a new senior inspector role to focus on technical development of staff across the organisation;
- Give greater priority to data management, security and risk, ensuring that we comply with our requirements under relevant Data Protection legislation and embedding privacy by design in all our processes;
- Retender for our IT support contracts;
- Give further consideration to alternative and additional income streams;
- Implement the recommendations of the shared services review with HFEA to improve the resilience of both organisations.



Resources – people and finance

Our people – workforce and leadership

	Q1	Q2	Q3	Q4
Starting count – payroll	44	45	48	49
Starting count – non-payroll	0	0	0	0
Expected transfers in – payroll	1	3	1	2
Expected transfers out – payroll	0	0	0	0
Changes in non-payroll staff	0	0	0	0
TOTAL at end quarter	45	48	49	51

As a small, expert regulator, the HTA has long recognised a strategic risk related to staff recruitment and retention – in particular our vulnerability to the loss of experienced staff undertaking our frontline regulatory work. In response to this risk, we implemented our People Strategy, which has gone some way towards mitigating our human resource risk through initiatives such as flexible working and a career development scheme. However, retaining staff expertise, the ability to recruit high quality candidates and the time to induct and train new members of staff have been identified as key areas we need to address to improve our resilience and sustainability.

In line with our strategic vision to be operating in a more sustainable, resilient and agile way by 2021, and as part of our organisational transformation programme, we will introduce key changes to our People Strategy in 2018/19. These will include a greater emphasis on remote working by design, a new approach to induction and training and a renewed focus on line management and developing our staff.

In further support of this vision, we intend to implement some structural changes aimed at ensuring we lead our people effectively through this period of change. We will consider the introduction of a new senior inspector role, focussed on providing technical expertise and leading on induction, training and quality assurance.

During 2018/19, it is expected that:

- the HTA will have 3.5 FTEs who are classified as executive senior managers, within the total of 51 FTEs;
- there will be one FTE Human Resources member of staff within the full complement of 51 FTEs;
- the training budget will equate to around 1.5 per cent of the pay bill;
- we do not anticipate any non-payroll staff.

In line with our strategic vision to be operating in a more sustainable, resilient and agile way by 2021, and as part of our organisational transformation programme, we will introduce key changes to our People Strategy in 2018/19.

As an organisation, we remain committed to continuous improvement and delivering value for money for both the public and the establishments who we licence.

Efficiency and productivity

We understand the impact that licence fees have on the establishments we regulate. However, after several years of making efficiencies, holding budgets steady and absorbing new work, in 2018/19 we have introduced an increase in the income from fees to maintain the high quality of our regulation and make the necessary improvements to our operations and infrastructure.

We continue to work hard to keep fee increases to a minimum, and seek opportunities to offset inflationary costs with income from other sources such as sub-letting part of our accommodation.

As an organisation, we remain committed to continuous improvement and delivering value for money for both the public and the establishments we license. We also recognise that 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 the importance of focussing on outcomes that really matter to the public and professionals.

To achieve this we will undertake work to develop a deeper understanding of those outcomes and the impact that they have on patient safety and public confidence. We will use the data we generate to inform our risk-based approach, identify trends and to share learning with our licensed establishments and the sectors we regulate.

In 2018/19 we will also consider how we can carry out further performance related work including how we make appropriate comparisons to know that we are delivering value for money.

The HTA has long-established links with other health arm's length bodies, including a shared staffing arrangement with the Human Fertilisation and Embryology Authority where our Director of Resources and Head of Finance work across both organisations. A recent review of the shared services arrangement concluded that the functions are delivered appropriately, however there are a number of recommendations centred on improving communication, rebalancing the weighting across roles and areas where further collaborative work could benefit both organisations. In 2018/19 we will implement

the recommendations – continuing to make the most of opportunities to deliver value for money, and improving our resilience by building on our strategic partnerships with other organisations.

Digital delivery and technology

The organisational transformation programme provides an opportunity for us to critically review how we use business technology to support our day-to-day work, and explore the contribution that systems and data can make to improving our agility and resilience as an organisation.

In 2018/19 we will update our information and communications technology strategy to reflect the changes required to deliver the programme. We recognise that effective use of technologies will be essential for success; in particular, we need to make the right technology choices about our IT infrastructure, cloud storage and application hosting, electronic document management and records management systems, telephony, conferencing technologies and shared virtual spaces.

We will map the data and information we need to conduct our functions efficiently and effectively, keeping the burden of regulation to the minimum necessary. We will also improve our digital offerings, updating our website content to make it easier to find the information our users need and streamlining our licence applications, variations and data submissions via the HTA portal.

Our program of work aimed at engaging with licensed establishments told us that Designated Individuals, and those working under a licence, would value opportunities to network, engage and share best practice. In 2018/19 we will launch an online community, aimed at providing those who work with human tissue with a platform to interact with each other and us as the regulator.

We take our responsibility for data protection and information security seriously. In 2018/19 we will implement the necessary controls to ensure compliance with the provisions of the General Data Protection Regulations and the Data Protection Act 2018. We will also continue to strive to meet our obligations under the National Data Guardian's data security standards and relevant UK Government cyber security frameworks.

Capital

Our operational transformation programme is at the heart of the HTA's Strategy 2018-21. The first year of the strategy will focus on more detailed planning, and as such we anticipate the bulk of capital expenditure relating to the programme to fall into subsequent years. During 2018/19 we require a £100k of funding for capital investment in order to lay the foundations for the future years of the strategy.

- System upgrades relating to cyber security risks and packages that are no longer supported by suppliers;
- Routine refresh of technology and equipment;

The purchase of home office equipment to ensure staff working from home have an appropriate working environment.

Finances

The HTA receives funding from two main sources. The majority (75 per cent) comes from licence fees, with the remainder provided as Grant-in-aid from our sponsor, the Department of Health and Social Care. We also receive a small amount of income for undertaking activities on behalf of the devolved administrations and from sub-letting part of our office space.

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.

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. We have robust financial procedures and policies in place and strict controls in relation to authorisation of expenditure

The high-level budget for 2018/19 is shown below:

	£000
Total Staff costs	3,346
Other costs	132
Total Corporate shared service costs	1,376
Total Costs	4,854
Total Income	4,854

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

Monitoring and measuring performance

Base line business plan indicators

Delivery KPIs	
Activity	Performance Indicator
Undertake a risk based inspection / audit programme	200 site visits to take place during the business year across all sectors (year-to-date)
Take appropriate action for all regulatory non-compliances	100% of Corrective and Preventative Actions (CAPAs) implemented to address critical and major shortfalls are completed to the HTA's satisfaction within agreed timescales or further regulatory action implemented (reported monthly)
Make appropriately evidenced decisions to agreed quality standards	100% of non-panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within five working days (average reported monthly)
Make appropriately evidenced decisions within agreed timeframes	100% of panel cases turned around in line with the quality criteria set out in the standard operating procedure, and within ten working days (average reported monthly)
Respond to enquiries in a timely way	At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries (reported monthly)
Make better use of our data to target our resources effectively	Report provided to the Authority annually (Q2) on the outcomes of our regulatory interventions and the impact on patient safety and public confidence
Development KPIs	
Activity	Performance Indicator
PROJECT: Deliver a project to implement EU Directives on Coding and Import / Export	Project red-amber-green (RAG) status remains amber or green during the course of the project (reported monthly) Embedding of requirements (Q1 onwards)
PROGRAMME: Deliver a licensed establishment relationships programme as per plan specification	To deliver the programme as agreed by HTA Management Group Elements of programme RAG status remain amber or green (reported monthly) Alpha testing of online community (Q1) Evaluation of options for DI training (Q2)

Development KPIs continued	
Activity	Performance Indicator
PROJECT: Assessment of Risk in the Human Application sector and update of processes to reflect this	Project RAG status remains amber or green during the course of the project (reported monthly)
	Approval of plans for proposed changes (Q3)
	Implementation of discrete changes (Q4)
Develop our People and ICT Strategies as the first step in planning our organisational transformation programme	Updated People and ICT strategies provided to Authority (Q2)
	Plans approved by HTAMG (Q3)

Deployment KPIs	
Activity	Performance Indicator
Reduce attrition rates through improved selection and targeted retention measures to retain staff	Attrition rate measured monthly on a rolling annual basis (high risk if more than 18%) (reported quarterly)
Implement targeted retention initiatives to better maintain capacity and improve capability among the Regulation Manager cadre, through improved selection and targeted measures to retain staff	Percentage of Regulation Managers with more than one year of service (high risk if less than 80%) (reported quarterly)
	Consideration of Senior Inspector role (Q1)
	Plan for remodelling of RM induction and training programme (Q1)
	Roll out of new programme (Q4)
Lead and advise on best recruitment procedures to maintain organisational capacity and capability	Number of vacancies reported monthly (high risk if more than three vacancies) (reported quarterly)
Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees	Actual income versus budgeted income (reported monthly)
	Actual spend versus budgeted spend (reported monthly)
	Actual cash reserves versus required reserve of £1.8m (high risk if deficit is more than 10%) (reported monthly)
Ensure that the HTA has sufficient financial resources to fund its regulatory and policy activity, whilst continuing to provide value for money to license fee payers through limiting growth in licence fees	Annual fees are calculated to recover no more than the net cost of HTA activity (total costs less Department of Health Grant-in-Aid and devolved governments income) (reported quarterly)
	Revisions to fees issued to stakeholders at least three months prior to implementation (reported quarterly)

Delivery PIs	
Activity	Performance Indicator
Issue draft inspection reports within agreed timeframes	At least 90% of draft inspection / audit reports are sent to the Designated Individuals / Licence Holders for a factual accuracy check within 20 working days of the end of the inspection/audit (reported monthly)
Finalise inspection reports and publish them on the HTA website within agreed timeframes	At least 90% of inspection reports are published on the HTA website within 10 weeks of the end of the inspection (reported monthly)
Seek feedback from establishments after each inspection and analyse and report the results each quarter	At least 80% of respondents rate the overall inspection process as either good or excellent (reported monthly)
Take appropriate action for all regulatory non-compliances	100% of audited corrective and preventative action (CAPA) plans have sufficient evidence provided to ensure that the shortfall has been addressed (reported quarterly)
Monitor use of inspection workbooks and carry out audits to review evidence supporting inspection findings	Audit of 10% of inspection workbooks across the sectors (reported quarterly)
Process licence applications and variations in accordance with standard operating procedures	At least 90% of completed applications to vary a licence are processed within 20 working days of receipt (reported quarterly)
Authorise preparation processes for tissues and cells for human application	A decision is reached on at least 90% of preparation process dossiers within 20 working days of receipt of the completed dossier or any additional information requested by the HTA (reported monthly)
Share learning gained from SAEARs reports received in the human application sector	Sector specific publication to include learning from SAEARs (Q4)
Ensure the quality of reports submitted by Independent Assessors	90% of Independent Assessor reports are fit for purpose on submission (reported monthly)
Complete annual Independent Assessor re-accreditation	Independent Assessor re-accreditation completed (Q4 18/19)
Keep under review the Service Level Agreement with NHSBT	Assess if NHSBT is delivering value for money through its Service Level Agreement (Q4 18/19) The SLA will be kept under review and revised if necessary

Delivery PIs continued	
Activity	Performance Indicator
Deliver annual panel training to Authority Members	All Authority Members undertake panel training (including induction for new Authority Members) in 2018/19 and agree that they feel confident in their role as decision makers on panel cases
The Authority secretariat service is effectively managed	<p>Delivery of four Authority meetings (one public meeting) and one strategic away day</p> <p>Support the Department with the appointment of Members, as well as their inductions and appraisals</p> <p>Members provide positive feedback for inductions</p>
The Authority and its committees operate effectively	<p>The Authority is able to hold the executive to account</p> <p>Feedback to be sought from Members (Q4)</p>
PROJECT: Produce the annual review publication (Q2) and organise the HTA's annual event for 2018 (Q3)	<p>Feedback from the event is positive, with 80% or more attendees reporting that the day was interesting, well run, and that they would attend again (and/or recommend it to others)</p> <p>Report submitted to SMT within two months of the event (Q3 18/19)</p> <p>Project RAG status remains amber or green during the course of the project (reported monthly)</p>
Publication of Business Impact Target (BIT) assessments for 2017/18	Publication of BIT related items on HTA website by Government deadline
Undertake benchmarking exercise against similar bodies (Q2)	Report provided to HTAMG (Q3)
Ensure that the content and architecture of our website is fit for purpose and accessible	Website content is updated in line with user feedback (Q1 – Q4)
Build on the insight gained from our public evaluation work and the development of the HTA's public panel	<p>HTA staff:</p> <ul style="list-style-type: none"> • are aware of the PEI work taking place for their sector • are involved and can contribute to ongoing work in their area • that PEI takes place as appropriate across each function • any new publications or processes are considered by our public panel for feedback

Delivery PIs continued	
Activity	Performance Indicator
Seek to increase awareness of the HTA's role, remit and associated licensing requirements with professional stakeholders	Communications plan developed by Q2.
Feedback to licensed sectors on the information gained from the 2017 compliance updates, inspections and incidents	Presentation at professional events (ongoing) Sector specific publications (Q3)
Update our Memoranda of Understanding documents as and when required, and continue sharing data	All Memoranda of Understanding and other bilateral agreements are kept up to date, adhered to and reviewed to ensure they remain effective: <ul style="list-style-type: none"> roll out of communications to all staff on detail of agreements and how to adhere to them in (Q2) review of content and decisions on updating made in (rolling, as required)
Respond to all requests in accordance with the Data Protection Act	All requests under the Data Protection Act responded to within 40 calendar days (reported quarterly)
Respond to all requests in accordance with the Freedom of Information Act	All requests under the Freedom of Information Act responded to within 20 working days. For all responses to be published within five working days of issue (reported quarterly)
Effective management of complaints in line with the policy	All complaints are acknowledged within three working days and investigated and responded to within 20 working days (reported quarterly)

Development PIs	
Activity	Performance Indicator
PROJECT: Sustainability of the Independent Assessor framework - Opportunities and threats facing the system	Project RAG status to remain green or amber during the course of the project
PROJECT: Codes and Standards Implementation Project	Report to Stakeholder Group (Q1) Feedback to sector (Q3) Project RAG status remains amber or green during the course of the project (reported monthly)

Development PIs continued	
Activity	Performance Indicator
PROJECT: Establish appropriate horizon scanning functions at the HTA	Project RAG status remains amber or green during the course of the project (reported monthly) Implement as business as usual activity (Q2)
Strengthen the HTA's formal arrangements for policy development	Structured policy framework to be agreed and rolled out (Q2)
Undertake policy work to provide clarity on the HTA's regulatory framework for stakeholders and support consistent decision making	Policies and guidance are published on the HTA website as required (ongoing) Collaborative work with DHSC on opt-out for organ donation (Q1 onwards) Planning work relating to EU Exit (Q1 onwards)
PROJECT: Authorisation of preparation processes in blood and tissues and cells (EU Project - 36 month duration)	Attendance at technical meetings - Q1 2018/19 onwards - twice per annum Final Report and meeting - Q4 2020/21
PROJECT: Reviewing how the HTA's stakeholder and sector groups operate to identify best practice and standardised processes that could improve remit delivery and efficiency	Project complete (Q1 18/19) Project RAG status remains amber or green during the course of the project (reported monthly)
PROJECT: Update of the licensing application and assessment process	Project RAG status to remain green or amber during the course of the project New process to be reviewed Q1.
Review and develop quality management and document management systems	Review and propose quality management processes (Q2) Making discrete changes to document management processes and procedures (Q3) Roll out across the system (Q4)
Develop the HTA Portal to receive and disseminate licensing information	New end to end business case in pipeline. Project outline document to HTAMG in Q3.
Develop CRM, Sharepoint and key IT systems in line with prioritised business needs	Changes identified, logged and delivered according to estimated budgets and agreed timelines CRM upgrade concluded in Q1

Development PIs continued	
Activity	Performance Indicator
Electronic Document Management System (EDRMS) requirements form part of business technology strategy	Decision making on existing systems (Q2 18/19) Business technology strategy approved by Authority (Q2)
Project: Implementation of relevant Data Protection legislation (GDPR and Data Protection Act 2018)	Project RAG status remains amber or green during the course of the project (reported monthly)
Implement the recommendations of the shared services review with HFEA to improve the resilience of both organisations	Implementation plan in place by Q3.

Deployment PIs	
Activity	Performance Indicator
Ensure staff understand the performance management process and that new staff receive training	100% of performance assessments completed and submitted by end of October 2018 for mid-year reviews and end of March 2019 for annual reviews
Ensure all existing HR policies meet the needs of the HTA and are up to date with good practice and current legislation	Current Human Resources policies are reviewed in line with expiry dates and new ones implemented in time for external change requirements
Monitor equal opportunities data	The HTA has a diverse workforce, as evaluated by annual equal opportunities reports (Q1 18/19)
Deliver an effective financial management and payments process - pay all suppliers within 10 working days, in accordance with Government's Best Payment Practice (BPP) Code	90% of payments made within 10 days of receipt of undisputed invoice (reported monthly)
Manage the HTA's finances to ensure sufficient funds are in place to meet payments required; appropriate spending; appropriate levels of reserves; debtor management	90% of licence fees received within 56 days of invoicing (reported monthly)
PROJECT: Deliver recommendations from the enquiries audit	Project RAG status remains amber or green during the course of the project (reported monthly)

Deployment PIs continued

Activity	Performance Indicator
Ensure the security of HTA information assets through compliance and awareness	<p>Zero personal data breaches</p> <p>Zero information security breaches</p> <p>Pay Data Protection Fee annually</p> <p>Staff inductions within two weeks and annual refresher training</p>
Make the best use of information and protect it appropriately	<p>Data Protection, Information Governance and Information Security strategies drafted (Q1)</p> <p>Data Protection, Information Governance policies updated and staff trained (Q2)</p> <p>Senior / Asset Information Owner training and meetings in place (Q2)</p>
Advise on and provide reliable IT	<p>No unplanned outages</p> <p>Laptop refresh (Q1)</p>
Manage IT contracts to maintain adequate contract arrangements with key suppliers	<p>Quarterly supplier assurances including the standard assurance template</p> <p>Transition to new IT contract to be completed in Q3.</p>
To maintain acceptable levels of internal audit recommendation - i.e. medium-low	<p>90% of audit recommendations are medium or low in their severity</p>
Ensure that purchase orders and in place as appropriate for all expenditure	<p>No more than one allocated purchase order per period</p>



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