HTA
Human Tissue Authority

Business Plan

2017/18

Contents

Introduction from the Chief Executive

We regulate in a way that supports innovation by ensuring we remain adaptable in the face of new and emerging science and technology

I am very pleased to be introducing the Human Tissue Authority's Business Plan for 2017/18. It sets out what will achieve in the second year of our three-year Strategy.

The Strategy aims to ensure the confidence of professionals working in the organisations we regulate and the public, by ensuring the safe and ethical removal, storage, and use of human tissues and organs, with proper consent. We do this in a way that supports innovation by ensuring we remain adaptable in the face of new and emerging science and technology.

We remain a small, but focused, organisation, with clear priorities to reduce our regulatory burden wherever we can, and to maximise value for the taxpayer. We strive to work with establishments that we regulate to encourage improvement, and foster an open and transparent reporting culture for the benefit of the public.

Looking back at the last year, we set ourselves ambitious delivery and development goals. We have made great progress on a number of projects that will deliver benefit for our licenced establishments and the public, in particular:

- new working practices, that will engender higher standards following the implementation of our revised Codes of Practice and Standards;
- the development of public guides to our Codes of Practice, which make our role and approach clearer to a wider audience;
- a successful consultation on, and implementation of, our revised fees structure;
- preparing the ground for the implementation of the European Union Directives on the Single European Code and the Import and Export of Tissues and Cells;
- providing expert advice on areas outside our core remit, but where there is a risk to public confidence, such as on pregnancy remains, taphonomy and cryopreservation.

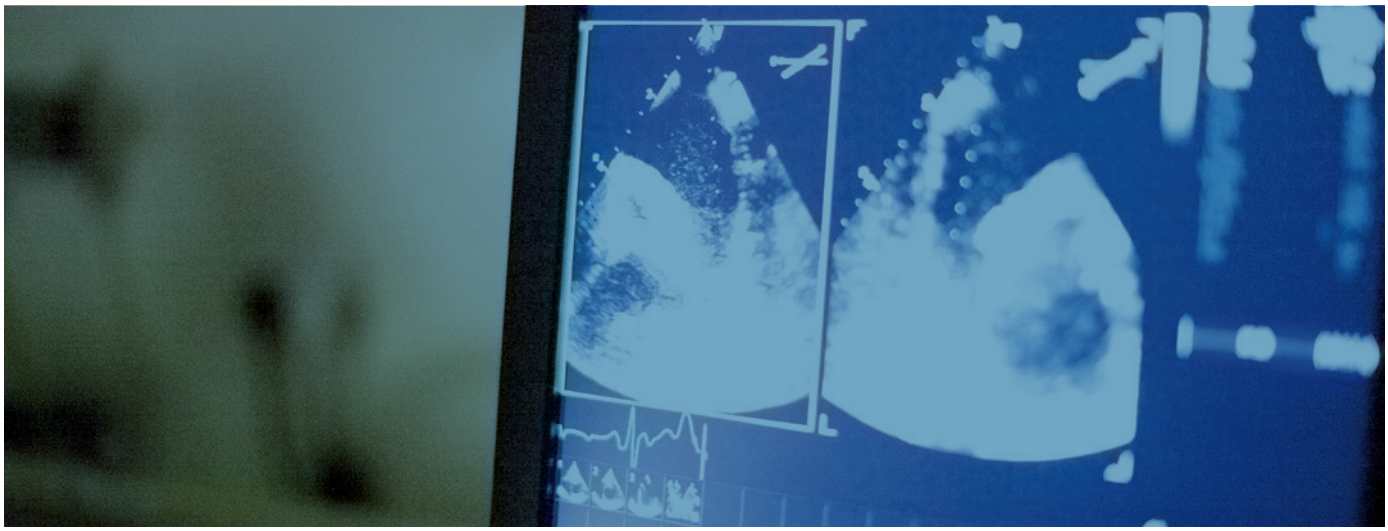
- involving professional and public stakeholders in innovative ways to ensure our work reflects the expert opinion and experience of those we regulate, as well as the wider public.

This Business Plan describes what we will be doing to add value in the year ahead.

At a time when science and technology continue to move at pace, innovative uses of human tissue must not come at the expense of public confidence; we at the HTA will continue to protect that confidence and, where necessary, adapt our approach to and ensure we address the emerging issues in the right way.

I look forward to another busy and challenging year for the HTA.

Allan Marriott-Smith
Chief Executive



Part One – About us

We license organisations that store and use tissue for purposes such as: research; human application; organ transplantation; post-mortem examination; teaching; and public exhibitions

Who we are and what we do

The HTA is an Executive Non-Departmental Public Body sponsored by the Department of Health. We were established under the Human Tissue Act 2004 (HT Act), which covers England, Wales and Northern Ireland, to regulate activities relating to the removal, storage, use and disposal of human tissue. The HTA also regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

The HTA has a number of statutory functions in England, Northern Ireland and Wales. We inform the public, professionals, and the Secretary of State for Health and Ministers for Health in Northern Ireland and Wales about issues within our remit. We meet our requirement to inform professionals by providing guidance, including through our Codes of Practice, updated versions of which will be launched in April 2017. We also meet our requirement to inform the public by providing information, to help them to make informed decisions.

We license organisations that store and use tissue for purposes such as: research; human application; organ transplantation; post-mortem examination; teaching; and public exhibitions. We license approximately 860 premises and publish Standards that they must meet on: consent; governance and quality systems (including traceability); premises, facilities and equipment; and disposal. We also inspect organisations to check that they maintain high standards and follow appropriate procedures.

As well as licensing under the HT Act, the HTA is the Competent Authority for European Union (EU) Directives. We are responsible for the EU:

- **Tissue and Cells Directives** (EUTCDs) – To ensure the quality and safety of human tissue and cells used for patient treatment.
- **Organ Donation Directive** (EUODD) – To ensure the quality and safety of organs intended for transplantation.

In 2017/18, we will be bringing into force two new EU Directives, which amend and implement areas of the EUTCDs, with respect to the coding, import and export of human tissues and cells in the human application sector.

The HTA also regulates, through an independent assessment process, the donation of solid organs from living people. We ensure that valid consent is given for organ donation and that no reward is sought or offered. We fulfil a similar role for living donation of bone marrow and peripheral blood stem cells from children and adults who lack the capacity to give consent.

The Authority – the HTA's non-executive board – is made-up of a Chair and eleven Members:

- nine are appointed by the Secretary of State for Health;
- one is appointed by the Welsh Minister of Social Services and Public Health; and
- one is appointed by the Minister of Health in Northern Ireland.

The Authority is made up both lay and professional Members and at the time of publication includes an organ donor and a transplant recipient. 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 Authority's primary role is to ensure that the HTA's statutory responsibilities are met and discharged effectively. It achieves this by setting the HTA's strategic direction and providing both support and challenge to an Executive, which is responsible for the delivery of these responsibilities on a day-to-day basis.

In line with Government requirements, this document is produced annually, and should be read in conjunction with the **HTA's Strategy**, which provides detail of the HTA's strategic approach and high-level objectives.

Our Strategy and Business Plan are underpinned by three core themes, which guide all activity undertaken by the HTA

Our priorities

The confidence of professionals and the public in the regulation of human tissue is central to our success. Building it shapes our day-to-day work, and protecting it is our first priority.

Our overall strategic purpose is to maintain that confidence by ensuring that the removal, storage and use of human tissues and organs is undertaken safely and ethically, and with proper consent.

Building on this, our Strategy and Business Plan are underpinned by three core themes, which guide all activity undertaken by the HTA:

- **Delivery** – How we achieve our strategic objectives today;
- **Development** – How we will improve in the future; and
- **Deployment** – How we effectively use our people and resources.

Our Business Plan sets out our ambitions for 2017/18. The HTA operates a continuous business planning process, which allows for the introduction of new planned activities when resources allow, and to introduce further activities that respond to changes in the regulatory environment. Alongside the statutory delivery functions outlined above, we have identified three priority development activities for the 2017/18 year. These are to:

- complete the delivery of a project to implement new EU Directives on Coding and Import / Export, which began in 2016/17;
- develop and deliver a relationship management programme for licenced establishments (previously referred to as Designated Individual engagement); and
- develop and deliver a project to assess risk in the human application sector (in addition to our standard risk assessment across all sectors), and to update our processes to reflect the project's findings.

The HTA's strategic aims, high-level objectives and key milestones for 2017/18 are set out in the next section. More detail is provided in the Baseline Business Plan 2017/18 – Deliverables on page 24, which lists our key performance indicators (KPIs) and performance indicators (PIs).

Our objectives and how we deliver them

Delivery – To deliver the right mix of activity to maintain public and professional confidence

Our Delivery objectives remain, to:

- Deliver right-touch regulation and high quality advice and guidance, targeting our resources where there is most likelihood of non-compliance and greatest risk to public confidence.
- 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.
- Deliver effective regulation of living donation.
- 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 2017/18, we will:

- Undertake and publish reports on a programme of site visits and inspections which meet the aims of the HTA, and licensed establishments, and which provide assurance to the public that standards are being maintained.
- Take a proportionate approach to our regulation, and ensure that where there are shortfalls against standards, these are rectified within agreed timescales.
- Ensure decisions on living organ donation cases meet agreed service standards in a way that provides the necessary protections.
- Engage with, and involve, the public and professional stakeholders in our work, seeking feedback and comment using a wide variety of channels on and offline.
- Conduct a public evaluation to measure what areas of our work the public are most interested in being involved in, and why.

Development – To make the right investment to continuously improve delivery

Our Development objectives remain, to:

- Reduce regulatory burdens where risks to public confidence are lowest.
- Make it clearer how to achieve compliance with new and existing regulatory requirements.
- Make continuous improvements to our systems and processes to minimise wasted or duplicated effort.
- Take opportunities to better inform and involve the public.

During 2017/18, we will:

- Continue to develop our approach to engaging with licensed establishments to increase compliance (previously referred to as Designated Individual engagement).
- Undertake a comprehensive assessment of risk across the human application sector and amend our processes as necessary (in addition to our standard risk assessment across all sectors).
- Based on the outcome of our independent enquiries audit, and the work undertaken by the enquiries improvement project, refine our processes to improve further the timeliness and quality of enquiry responses.
- Implement the EU Directives on Coding and Import / Export, working with establishments to ensure as smooth a transition as possible.
- Carry out a content review of the public information on our website, and continue to develop new material – with input from the public – which is widely shared; this is to improve public understanding of what we do, and what we expect from those we regulate.
- Continue to upgrade and develop our Customer Relationship Management (CRM) system, website, and online portal to better meet our business needs.

Deployment – To make the most effective use of people and resources in pursuit of our goals

Our Deployment objectives remain, to:

- Manage and develop our people in line with the 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.

During 2017/18, we will:

- Deliver on the commitments in the People Strategy, in line with its associated road map, which includes a commitment to consult staff on emerging issues and relative priorities.
- Ensure the best use of office space to control accommodation costs, through:
  - the promotion of flexible working;
  - efficient use of existing space; and by
  - ensuring each team can effectively manage their own areas.
- Undertake a re-tendering exercise for our IT support services.
- Provide opportunities for HTA staff and Authority Members to come together to encourage greater understanding of shared goals and priorities.

The HTA has developed, and is implementing, a People Strategy to strengthen our offer to staff

Resources – people and finances

Our people

Full time equivalents (FTEs)

	Q1	Q2	Q3	Q4
Starting count – payroll	51	51	51	51
Starting count – non-payroll	0	0	0	0
Expected transfers in – payroll	0	0	0	0
Expected transfers out – payroll	0	0	0	0
Changes in non-payroll staff	0	0	0	0
TOTAL at end quarter	**51**	**51**	**51**	**51**

The HTA manages a number of strategic risks, one of which is related to an inability to carry out our statutory remit. The key factor underpinning this risk is the availability of experienced staff to undertake our frontline regulatory work. We plan to maintain our overall headcount of 51 in 2017/18, which is supported by our income plans.

Staff turnover (which for the 2015/16 business year was approximately 30%) and maternity leave are ongoing issues for the HTA. We have a range of measures to retain staff, including more flexible working and a career development scheme, which allows staff to apply for funding for additional training, on the agreement that they stay with the organisation for a specified period following completion of the course.

These steps have gone some way towards mitigating the human resource risk, although the HTA remains subject to the continued risk of staff turnover in the face of the relatively limited career development opportunities available in an organisation of its size.

In response to this challenge, the HTA has developed, and is implementing, a People Strategy to strengthen our offer to staff. Alongside this, business planning activities for 2017/18 will include the identification of development opportunities where staff may be seconded to work on the delivery of discreet projects to further develop their skills. There are no expected reductions from natural wastage and redundancy.

During 2017/18, it is expected that:

- the HTA will have 3.5 FTEs who are classified as very 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 two per cent of the pay bill; and
- there will be no non-payroll staff.

Finances

The HTA receives funding from two main sources. The majority (nearly 80 per cent) comes from licence fees, with the balance coming from our sponsor in Grant-in-Aid – the Department of Health. We also receive a small amount of income for undertaking activities on behalf of the devolved governments and sub-letting part of our office space.

The licence fee income pays for a wide variety of activities associated with our regulatory remit – from evaluating licence applications, making licensing decisions and issuing licences, through to site visit inspections and providing advice and guidance to licensed establishments.

We place great importance on ensuring that our finances are managed efficiently, effectively and in a way, which minimises risk. The high-level budget for 2017/18 is shown below:

Income	£000s
Department of Health funding	703
Licence fees	3,388
Other income	508
Total income	**4,599**

Expenditure	£000s
Operating costs	
Staff costs	2,995
Other operating costs	1,331
Total operating costs	4,326
Depreciation charges	273
Total revenue expenditure	**4,599**

Capital

During 2017/18, the HTA must embark on two significant IT upgrades. The first is a physical refresh of its IT hardware; both laptops and server infrastructure. The HTA delayed this upgrade some 18 months ago by reinvigorating its existing hardware with new hard disk drives and processors. This was only a temporary measure, and it is now necessary to embark upon a full IT refresh in 2017/18.

A second piece of work is required to amend and upgrade the HTA's main CRM system. The current CRM system is the Microsoft Dynamics package, the current operating version of which, will cease to be supported by Microsoft at the end of 2017. As such, it is necessary that the HTA undertakes an upgrade before the end of 2017, to ensure this essential software remains supported. In addition to the upgrade, the HTA must undertake significant system amendments in order to support the introduction of the new EU Directives for Coding and Import / Export of human tissue.

Although the licence upgrade itself is not expensive, the bespoke level of code that is in use will mean the review, amendment, and testing process required to ensure that the upgrade and amendments are successfully implemented, will be significant for an organisation of our size.

Overall, the HTA will require funding for capital investment from the Department of Health of £250,000 in 2017/18.

The HTA's IT Strategy is refreshed every year to ensure IT supports the HTA's business

Making the most of our resources

The Director of Resources oversees the procurement of goods, services and contracts. Our Procurement Strategy and governance arrangements are set out within HTA policies and centralised solutions for spend wherever possible are used.

The HTA is aware of the Department of Health and Cabinet Office / Efficiency Reform Group's efficiency controls and procedures; these are understood and will be followed. The HTA will comply with data requests and publication of data arising from the Government's transparency agenda. All requests will be dealt with as rapidly as possible, while ensuring quality.

The HTA rents space in a Department of Business, Energy and Industrial Strategy managed building, along with other arm's length bodies. We continue to seek opportunities to gain the greatest value for our accommodation, having reduced the space the HTA occupies and having extended our arrangement to make more workstations available to our neighbours, the NHS Litigation Authority.

During 2017/18, we will be reviewing our occupancy of our current offices and will be working with colleagues in the Department and the Government Property Agency to consider options in relation to a potential move to Government-owned estate within London.

The HTA's IT Strategy is refreshed every year to ensure IT supports the HTA's business. The HTA has outsourced provision of IT services for some years. The present contract has been extended to 2017 and it is expected that the HTA will undertake a procurement exercise for IT services in 2017/18. Any procurement that takes place would follow the necessary frameworks and principles.

With regard to information governance, the Director of Resources is the Senior Information Risk Owner, and Information Asset Owners are in place. The HTA assesses information risk at least once a year, using the Government's Security Policy Framework.

Efficiencies

The Grant-in-Aid made available to the HTA has reduced by 34 per cent since 2010. Grant-in-Aid funds our work on the assessment of living organ donations and bone marrow / peripheral blood stem cell donations. It also funds those administrative and support functions, which are not directly associated with our work with licensed establishments.

We have reduced licence fees over the same period by making further efficiencies that enable us to manage with 38 per cent less income from licence fees. The HTA is now a very lean organisation and there are only small opportunities to make further savings, which are largely offset by inflation increases.

We understand the importance of keeping licence fees as low as possible, recognising that licensed establishments live in challenging financial times. At the same time, we must continue to be an effective regulator and we seek to strike the right balance. This has meant small increases in fees over recent years; however, we continue to work to keep these at a minimum while still ensuring public confidence. We make sure that reductions in Grant-in-Aid are matched by reductions in the cost of activities funded by Grant-in-Aid and that no cross-subsidisation takes place.

Part Two – How we work with others

Collaboration has always been a key theme for the HTA and we are committed to working with partners in the health sector and with the public as a whole

Working in partnership

The HTA maintains an ongoing commitment to working collaboratively with Government, other regulators and the third sector. Collaboration has always been a key theme for the HTA and we are committed to working with partners in the health sector and with the public as a whole. Here we set out examples of our ongoing and planned future collaborations:

- **Research sector:** Our collaborative work becomes stronger each year. This is demonstrated through an HTA staff member working one-day-per-week at the Health Research Authority (HRA). This allows us to drive forward joint pieces of work, improving the efficiency of how we work together. This practical partnership, along with our long-standing memorandum of understanding and membership of the HRA's Collaborative and Development Forum, ensures that those involved in regulated research can be assured of a consistency of guidance, approach and a high-degree of information-sharing between our two organisations.

  We are also continuing to work with NC3Rs, the organisation that leads on the discovery and application of new technologies and approaches to replace, reduce and refine the use of animals for scientific purposes. Our joint work seeks to support scientists accessing and using human tissue for research, and includes the development of new on-line resources.

Although we have no role in the regulation of data, the growing interest in the use of tissue-derived data in research means that we continue to play an increasing role in informing the debate, particularly around matters of consent.

- **Post-mortem sector:** We continue to build strong and constructive relationships with a range of professional stakeholder groups, including the Royal Collage of Pathologists, the Association of Anatomical Pathology Technicians (the professional body for anatomical pathology technologists), the Coroners Society of England and Wales and the Home Office Forensic Science Regulation Unit. These bodies are represented on our Histopathology Working Group, and contribute actively to policy development that affects the post-mortem sector.

  As the landscape in the post-mortem sector changes in light of scientific and technological advancements, we are working to develop new alliances that will help us maximise the benefits of regulation and maintain public confidence that the use of bodies and human tissue is governed by systems that recognise the primacy of consent and maintain the dignity of the deceased.

- **Human application sector:** We continue to work closely with colleagues at the Medicines and Healthcare products Regulatory Agency (MHRA) and the Human Fertilisation and Embryology Authority (HFEA) to deliver our regulatory functions, whilst further exploring opportunities to reduce regulatory burdens on those establishments that are jointly regulated by our organisations. In the last twelve months, we have undertaken a number of joint or linked inspections. We will look to carry out more of them in the coming year, where the opportunity arises. Feedback from establishments will continue to shape this process, to ensure that it delivers a proportionate and efficient inspection process without increasing the risk to patient safety.

  We will also continue to work closely with the MHRA and HFEA, and other agencies working in healthcare sector, to ensure that there are robust mechanisms in place to support effective information sharing. In December 2016, the HTA and MHRA signed a partnership agreement promoting further collaboration between our organisations and strengthening the commitment to work together for the benefits of patients, staff, and stakeholders and to enhance regulation. In keeping with this agreement, and memoranda of understanding with other regulators, the HTA will also continue to support initiatives aimed at supporting the sector through effective collaborative working. This includes the continuation of our contribution to the effective running and development of the Regulatory

Advice Service for Regenerative Medicine (RASRM), the carrying out of joint investigations and the support of stakeholders, through the participation in joint meetings and through the development of joint guidance and position statements.

As the United Kingdom's Competent Authority for the EU Directives on the quality and safety of tissues and cells used in human application, the HTA will continue to work in partnership with competent authorities in other Member States, to facilitate the implementation of the EU Directives on Coding and Import / Export. We will also continue to work with other competent authorities to investigate any allegations about the quality and safety of products manufactured in, or imported into the EU, and to share information and learning about serious adverse events and reactions.

- **Anatomy sector:** We continue to work with the Anatomy Associations Advisory Committee (AAAC), formerly the Professional Guidelines and Practices (Anatomy) Committee, whose membership includes representatives of the three professional bodies within the anatomy sector, namely: the Anatomical Society (AS); the British Association of Clinical Anatomists; and the Institute of Anatomical Sciences (IAS). Working with AAAC allows us make a trusted, constructive and effective impact within a small sector. The work arising from this group has led, and will continue to lead, to new and improved guidance for people working in the sector.
- **Public display sector:** This is our smallest sector and is considered to be one of the lowest risk because of the static nature of collections and established systems governing the care of human remains in museums. This makes it all the more important that the HTA works with its stakeholders to ensure that our regulation is effective but proportionate. As well as continuing to participate in sector-led events on the display of human material, the HTA will be increasing its engagement with licensed establishments in this sector to provide on-going advice and guidance on our requirements and bring them together to facilitate the exchange of good practice between them.
- **Organ donation and transplantation sector:** We continue to work with NHS Blood and Transplant (NHSBT) operationally to avoid duplication of reporting or information gathering for the purposes of the Organ Donation Directives, to limit the burden on those working in this area.

  We also meet with senior colleagues at NHSBT to ensure we are able to provide strategic support when appropriate and also realise any efficiencies which may be delivered by working in partnership.

  In the human application sector, as the Competent Authority for the Organ Donation Directive, we work with other Member States to ensure

the Directive is being applied consistently and to share information as appropriate with the aim of delivering better patient outcomes.

In regard to our role in assessing living organ donation and bone marrow / peripheral blood stem cell cases, we continue to work with charitable organisations such as "Give a Kidney" and "Anthony Nolan" to ensure they are clear on the regulatory requirements and to provide information and guidance to support media campaigns.

Stakeholder and public involvements

Last year, we reviewed our joint working protocols and memoranda of understanding with a number of our stakeholders, including the MHRA, HRA and the National Research Ethics Service (NRES). These understandings set out how we share information, should concerns arise about establishments that are co-regulated or licenced by these organisations. Where possible, we will seek to minimise the burden of regulation for all our establishments, through methods such as joint inspections.

Public engagement and evaluation

We continue to identify opportunities to work with members of the public and public-facing organisations, to better inform the public about the work the HTA carries our across all of the sectors we regulate.

We have consulted our online public panel on the development of the public-facing summaries of our updated Codes of Practice and guiding principles, as well as asking for feedback on our **guide for the public on post-mortem scanning** (post mortem examinations which do not require the body to be opened).

We intend to seek both professional stakeholder and public feedback on any new publications, processes, or developments as part of our usual process, where time allows. To facilitate this process, we are looking to establish an online forum for the public and professionals, to provide a space for discussion, feedback, and general two-way dialogue with our audiences.

We will also carry out a public evaluation in 2017, to better understand what is of most interest and important to the public regarding human tissue regulation, and how to best involve them to ensure that the public voice is at our heart.

We will continue listen to concerns and seek to address these through the development and dissemination of guidance and information for the public on matters within our remit, as well as signposts to other organisations as appropriate.

Increasing our level of public involvement is a key priority for 2017/18. We will gain valuable insight from our public evaluation work, which will allow us to better target our communications and engagement efforts in ways best aligned with the public's own priorities.

Stakeholder engagement and evaluation

The HTA's Stakeholder Group continues to provide valuable insight and advice on a range of regulatory issues following its formation in 2013. To complement the work carried out by Group, we are looking to set up a more structured programme of engagement with establishments.

In addition, our Histopathology Working Group and Transplant Advisory Group play significant roles in the development of regulatory policy relating to the post-mortem and transplantation sectors respectively.

All of our groups draw their membership from our regulated sectors and provide an important opportunity for dialogue on and quality assurance of all aspects of our work. We are currently reviewing how our stakeholder groups deliver their remits, to ensure that their work assists us to respond effectively to changes in the regulatory environment through policy development.

Every three years, we run an evaluation of both professional stakeholder and public sentiment; this year, as mentioned above, we are focusing this on the public.

We will continue to engage with and encourage feedback from professionals, but this year we have a key commitment to focus more on our public engagement work. Additionally, the last couple of years has seen us ask for a lot of feedback from establishments – including submissions for our Triennial Review – and because of this, we have a better understanding of sentiment for this audience.

EU Directives on Coding, Import and Export

During 2017/18, we will continue our work with the Department of Health on implementation of the EU Directives on Coding and Import / Export, which will affect establishments in our human application sector. Our priority is to ensure that our licensed establishments are supported to comply with the new requirements, through provision of advice and guidance and proportionate licensing and inspection processes.

Working with devolved governments

The HTA's continues to work with devolved governments across the United Kingdom on matters of shared interest, providing advice and sharing information as appropriate.

Having produced the Code of Practice to support the Human Transplantation (Wales) Act 2013 and having a role in super-intending the legislation, we continue to work closely with the Welsh Government to provide advice and guidance as necessary, while also gaining an insight into how the new legislation is operating.

We have provided input to recent proposals for an opt-out system for deceased organ donation in Scotland, and will continue to provide support and insight from our experience of regulating in England, Wales and Northern Ireland, as these plans develop over the coming year.

Shared services

The HTA has established strong collaborative links with other arm's length bodies. With regard to staffing, our Director of Resources and Head of Finance work across both the HTA and the HFEA. We have other more informal links in place with other health bodies and the Department of Health to share expertise and good practice, and use the shared arrangements for legal advice and internal audit. We keep under review the potential to share more services with other organisations, and will progress these where they are cost effective and meet our needs and those of others.

Representation

The HTA plays an active role in a number of groups and committees in order to share our experience and knowledge and gain insight from others. These include:

- the Government's Regenerative Medicine Expert Group;
- the Welsh Government's Transplantation Advisory Group;
- NHSBT's 2020 Strategy Oversight Group;
- the Home Office's Forensic Pathology Specialist Group;
- the Advisory Committee on the Safety of Blood, Tissues and Organs, as well as
- the Joint Accreditation Committee of ISCT and EBTM (JACIE) – a standards and accreditation body focussed on bone marrow transplant units.

We also provide advice and guidance to organisations and individuals on an ad-hoc basis.

Licensing and inspection review outcomes / development programme

Our development programme continues to build on the outcomes of our review of licensing and inspection processes, in addition to responding to issues raised within the sectors we regulate and implementing our obligations in relation to the Government's better regulation initiatives on the Growth Duty and Business Impact Target.

We remain committed to continuously improving our systems are processes. Key development areas include better targeting of the inspection cycle to risk in the human application sector, including oversight of licensable activities carried out by third parties, clarifying regulatory requirements on a number of complex licensing matters and making better use of technology to make our processes more efficient.

Licencing fee review

In 2017/18, we revised our fee structure to better reflect where our regulatory activity is undertaken. In November 2016, our Authority agreed a small increase to our fees for the first time since 2010, in order to recruit two additional Regulation Managers, to further enhance our regulatory capability.

We continue to review our processes to streamline them as much as possible and to keep them effective. This should minimise any burden on our licensed establishments, although it is unlikely to result in further savings for the HTA. We are committed to working collaboratively with other regulators and organisations, including the Department of Health, to be efficient and to realise benefits for those we regulate, and to deliver better regulation. We have undertaken a review of our activities in line with better regulation initiatives and burden tests including the Business Impact Target.

The HTA is committed to taking a proportionate and risk-based approach to regulation, seeking to add value to the activities undertaken by our licence holders, and supporting opportunities for innovation and growth

Innovation and growth

The HTA recognises that many of our stakeholders work at the cutting edge of science and medicine, often pushing the boundaries of conventional regulation. We will continue to work closely with other regulators in the field (MHRA, HRA and HFEA) to clarify regulatory pathways, and remain committed to the provision of free, high quality advice and guidance to all stakeholders.

We will continue to work in partnership with the Department of Health to identify and explore ways of working which support organisations to comply and grow, within the confines of our legislation, and to ensure any legislative issues are raised appropriately.

During 2017/18, we will further embed the requirements of the Government's Growth Duty. The HTA has a strong record of accomplishment in ensuring that regulatory action is only taken when it is needed, and any action is proportionate. We will continue to use and develop our established stakeholder engagement channels to fully understand the environment that we operate in, the challenges faced by those we regulate and the impact of our activities, whilst ensuring that our key aim of ensuring the safe and ethical use of human tissue remains paramount.

Annex A

Baseline Business Plan 2017/18 – Deliverables

Key Performance Indicators (KPIs)

Reference	Detailed business activity	Indicator
Delivery KPI	Undertake a risk based inspection / audit programme	At least 210 site visits to take place during the business year across all sectors (year-to-date)
Delivery KPI	Take appropriate action for all regulatory non-compliances	100% of Corrective and Preventative Actions (CAPAs) implemented to address major shortfalls are completed to the HTA's satisfaction within agreed timescales or further regulatory action implemented (reported monthly)
Delivery KPI	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)
Delivery KPI	Make appropriately evidenced decisions within agreed timeframes	100% of panel cases turned around within ten working days (average reported monthly)
Delivery KPI	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)
Delivery KPI	Ensure human tissue is used safely	Report provided to the Authority annually (in May / June) on a series of measures, which provide an overview of safety in the regulated sectors

Reference	Detailed business activity	Indicator
Development KPI	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)
Development KPI	PROGRAMME: Deliver a licenced 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)
Development PI	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)
Deployment KPI	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)
Deployment KPI	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 85%) (reported quarterly)
Deployment KPI	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)
Deployment KPI	Manage all development options offered to staff and evaluate courses to ensure quality delivery and learning effectiveness	80% of staff attending training courses agree that the skills and knowledge gained will be useful for knowledge, performance, career development or general wellbeing (training statistics to be reported quarterly)

Reference	Detailed business activity	Indicator
Deployment KPI	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)
Deployment KPI	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)

Performance Indicators (PIs)

Reference	Detailed business activity	Indicator
Delivery PI	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)
Delivery PI	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)
Delivery PI	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)
Delivery PI	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 monthly)
Delivery PI	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)
Delivery PI	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 monthly)
Delivery PI	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)
Delivery PI	Share learning gained from SAEARs reports received in the human application sector	Development of a strategy to disseminate learning (Q1 17/18)
Delivery PI	PROJECT: Undertake Disclosure and Barring Service checks for Accredited Assessors	Ensure all Accredited Assessors have valid DBS / PVG checks in place (Q2 17/18) Project RAG status remains amber or green during the course of the project (reported monthly)

Reference	Detailed business activity	Indicator
Delivery PI	Revise the Guidance to transplants teams and Independent Assessors	Revise and publish (Q1 17/18)
Delivery PI	Ensure the quality of reports submitted by Independent Assessors	90% of Independent Assessor reports are fit for purpose on submission (reported monthly)
Delivery PI	Complete annual Independent Assessor re-accreditation	Independent Assessor re-accreditation completed (Q4 17/18)
Delivery PI	Keep under review the Service Level Agreement with NHSBT	Assess if NHSBT is delivering value for money through its Service Level Agreement (Q4 17/18) The SLA will be kept under review and revised if necessary
Delivery PI	Deliver annual panel training to Authority Members	All Authority Members undertake panel training (including induction for new Authority Members) in 2017/18 and agree that they feel confident in their role as decision makers on panel cases
Delivery PI	The Authority secretariat service is effectively managed	Delivery of four Authority meetings, one public meeting, one strategic away day Support the Department with the appointment of Members, as well as their inductions and appraisals Members provide positive feedback for inductions
Delivery PI	The Authority and its committees operate effectively	The Authority is able to hold the executive to account Feedback to be sought from Members (Q2 17/18)

Reference	Detailed business activity	Indicator
Delivery PI	PROJECT: Organise the HTA's annual event for (27 June) 2017 and produce the annual review publication	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) Report submitted to SMT within two months of the event (Q2 17/18) Project RAG status remains amber or green during the course of the project (reported monthly)
Delivery PI	Generation of Business Impact Target (BIT) assessments for 2015-17 and 2017/18 and publication of BIT score	Publication of BIT related items on HTA website by 9 June 2017 (for 2015-17 reporting period): - a list of all RPC-validated QRPs, with the relevant BIT score attached to them - a validated summary list of NQRPs - generation of BIT assessments for all QRPs implemented during 2017/18
Delivery PI	Continue to implement and embed the HTA's duties with regards the Growth Duty and wider government better regulation initiatives	Standard operating procedures and policies are updated to reflect the Growth Duty requirements (Q1 17/18) Training on Growth Duty requirements delivered to staff (Q1 17/18) Reporting on compliance with Growth Duty considered as part of annual reporting cycle (Q2 17/18) Respond effectively to requests for Burden Reduction Plans and related information
Delivery PI	Effectively show progress against the HTA's triennial review recommendations	Communicate externally and report on the delivery of the action plan within a week of the triennial review being published Bi-monthly update provided to SMT and on the website until a time that all actions are complete

Reference	Detailed business activity	Indicator
Delivery PI	Ensure that the content and architecture of our website is fit for purpose and accessible	Digital (website and newsletter subscribers) survey takes place in February / March 2017 80% of respondents say that they find the website easy to use, the content useful, and they can find the information they are looking for a follow up survey will take place to measure: • following improvement work based on the survey feedback • where a need for improvement has been identified (Q4 17/18)
Delivery PI	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: • roll out of communications to all staff on detail of agreements and how to adhere to them in (Q1 17/18) • review of content and decisions on updating made in (Q2 17/18)
Delivery PI	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)
Delivery PI	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 response to be published within five working days of issue (reported quarterly)
Delivery PI	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 PI	PROJECT: Codes and Standards Implementation Project	Post implementation review (Q2 17/18) Report to Stakeholder Group (Q3 17/18) Project RAG status remains amber or green during the course of the project (reported monthly)

Reference	Detailed business activity	Indicator
Development PI	PROJECT: Establish appropriate horizon scanning functions at the HTA	Project RAG status remains amber or green during the course of the project (reported monthly)
Development PI	Strengthen the HTA's formal arrangements for policy development	For a structured policy function to be agreed and rolled out (Q2 17/18)
Development PI	Undertake policy work to provide clarity on the HTA's regulatory framework for stakeholders and support consistent decision making	Publication of policies and guidance on: • hub and satellite arrangements (Q2 17/18) • cross-sector licensing (Q4 17/18) • licence variations (Q1 17/18) • regulatory action (the use and publication of Directions and Conditions) (Q1 17/18) • Medical Devices Directive (Q1 17/18) • Borderline Products (ongoing)
Development PI	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	Develop project outline document for consideration by HTAMG (Q2 17/18) Project complete (Q3 17/18) Project RAG status remains amber or green during the course of the project (reported monthly)
Development PI	Undertake an information gathering exercise to assess mortuary capacity and contingency arrangements and support NHS England's winter planning arrangements	Activity to be included in the post-mortem sector compliance update as part of the wider project to gather information from establishments regulated under the Human Tissue Act (Q2 17/18)
Development PI	Review and develop quality management and document management systems	Review and propose quality management processes (Q4 17/18) Making discrete changes to document management processes and procedures (Q4 16/17) Roll out across the system (Q1 17/18)
Development PI	Develop the HTA Portal to receive and disseminate licensing information	Certificates online Application/Variation forms online Better integration with website (Q1 17/18)

Reference	Detailed business activity	Indicator
Development PI	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
Development PI	Maintain the HTA wiki (internal communications) system	Wiki support contract in place (Q1 17/18) Wiki upgraded (Q1 17/18) Wiki UAT in place (Q1 17/18)
Deployment PI	Provide opportunities for Authority and HTA Staff to interact	Staff interact with Members at quarterly Authority meetings and sector specific training and policy sessions Feedback sought following each session from staff and Members (reported quarterly)
Deployment PI	Ensure staff understand the performance management process and that new staff receive training	100% of performance assessments completed and submitted by end of October 2017 for mid-year reviews and end of March 2018 for annual reviews
Deployment PI	Undertake a review of the HTA induction process	80% of new starters rate induction process as helpful and effective Results reported to SMT six monthly (Q3 and Q4 17/18)
Deployment PI	Ensure all existing 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
Deployment PI	Monitor equal opportunities data	The HTA has a diverse workforce, as evaluated by annual equal opportunities reports (Q1 17/18)
Deployment PI	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)

Reference	Detailed business activity	Indicator
Deployment PI	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)
Deployment PI	Provide operational support to all HTA colleagues	All travel and accommodation is booked six weeks in advance prior to travel where possible
Deployment PI	PROJECT: Deliver recommendations from the enquiries audit	Develop and approve a project outline document for consideration by HTAMG in (Q3 17/18) Project RAG status remains amber or green during the course of the project (reported monthly)
Deployment PI	Ensure the security of HTA information assets through compliance and awareness	Zero data security incidents Data Protection Registration renewed annually Staff inductions within two weeks and annual refresher training
Deployment PI	Make the best use of information and protect it appropriately	Information strategy drafted Data Protection and Information Governance policies updated and staff trained Senior / Asset Information Owner training and meetings in place (Q2 17/18)
Deployment PI	Annual information asset housekeeping	Affected assists cleared and audit trail complete
Deployment PI	Advise on and provide reliable IT	No planned outages
Deployment PI	Manage IT contracts to maintain adequate contract arrangements with key suppliers	Quarterly supplier assurances including the standard assurance template Smooth transition to and satisfaction with new IT contract(s)

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