HTA
Human Tissue Authority

Business Plan

2016/17

Contents

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 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 provide guidance, including Codes of Practice and Standards to professionals, and information to the public to assist them in making informed decisions on matters relating to our remit.

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 850 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 in the UK responsible for ensuring the quality and safety of human tissue and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directives (EUTCDs). We are also the UK's Competent Authority for the European Union Organ Donation Directive (EUODD), ensuring the quality and safety of organs intended for transplantation.

The HTA regulates, through an independent assessment process, the donation of solid organs from living people, ensuring that valid consent has been given, 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 consent to the procedure[1]. The HTA regulates living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.

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; one Member appointed by the Minister for Health and Social Services in Wales, 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'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 for 2016 to 2019, which provides detail of the HTA's strategic approach and high level objectives for the three years beginning 1 April 2016.

1 www.hta.gov.uk/sites/default/files/Code_of_practice_1_-_Consent.pdf

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 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 goal 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** – to deliver the right mix of activity to maintain public and professional confidence;
- **Development** – to make the right investment in development to continuously improve delivery;
- **Deployment** – to make the most effective use of our people and resources in pursuit of our goals.

Our business plan sets out our ambitions for 2016/17 and provides a baseline for the identification of future priorities. The 2016/17 business year will see the HTA take its first steps towards the development of a continuous business planning process. This process will result in a business plan that is reviewed and updated regularly, and which identifies our proposed business activity over a three-year period.

Alongside the statutory delivery functions outlined above, we have identified five critical development projects for 2016/17. The majority of these projects continue work that began in the 2015/16 business year, and seek to deliver a further improved regulatory experience for our licence holders. These projects are:

- to deliver a programme of communication and training to licensed establishments on our revised licensing Standards, which will come into force in 2017;
- to continue to work towards the implementation of the European Union Coding and Import Directives in 2017[2];
- to undertake a full review of our licensing fees structure;
- to develop further our approach to involving the public in all aspects of our work, and;

2 www.hta.gov.uk/policies/changes-coding-and-import-human-application-establishments

- to strengthen our strategic relationship with Designated Individuals (DIs) and Independent Assessors (IAs), including via training.

The Department of Health conducted a Triennial Review of the HTA's form and functions between June and December 2015. The HTA worked closely with the review team and the report's recommendations will be incorporated into our business plans for 2016/17. The report and its recommendations are due to be published in Spring 2016.

The HTA's strategic aims, high level objectives and key milestones for 2016/17 are set out in the next section. This information is supported by the 'Baseline Business Plan 2016/17 – Deliverables' which lists our key performance indicators (KPIs) and performance indicators (PIs) on page 23-29, which sets out our key performance indicators for this period.

Our objectives and how we will deliver them

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

Our delivery objectives for 2016/17 are to continue:

a) 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 the public

b) To 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

c) To deliver effective regulation of living donation

d) To 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

e) To maintain our strategic relationships with other regulators operating in the health sector

During 2016/17, 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
- Ensure that, where there are shortfalls against licensing Standards, these are rectified within agreed timescales
- Reach decisions on living organ donation cases to agreed service standards and in a way which provides the necessary protections
- Provide high quality responses to enquiries from professionals and the public
- Actively communicate with professional stakeholders and the public about matters within our remit using a wide variety of channels
- Seek to exert influence in Europe and internationally in matters relating to the regulation of organ donation and transplantation, and tissues and cells for human application

Development – To make the right investment to continuously improve delivery

Our development objectives for 2016/17 are:

a) To reduce regulatory burden where risks to public confidence are lowest

b) To make it clearer how to achieve compliance with new and existing regulatory requirements

c) To make continuous improvements to our systems and processes

d) To take opportunities to better inform and involve the public

During 2016/17, we will:

- Build on the outcomes of our review of licensing and inspection processes and other known improvement targets to produce an HTA development programme. In 2016/17 this will include:
  - Introduction of the European Union Coding and Import Directive
  - Designated Individual development
  - Independent and Accredited Assessor development
- Refine our processes to further improve the timeliness and quality of enquiry responses
- Develop and more widely communicate public-facing information which improves understanding of what we do, what to expect from those we regulate, and which promote informed consent. Examples will include:
  - Summary guides to the HTA Codes of Practice
  - Public guides to research, brain and body donation
- Improve arrangements for the public to inform and assure our regulatory approach
- Seek further opportunities to collaborate with others to reduce regulatory burdens, clarify regulatory pathways and assure our regulatory approach
- Act on the recommendations of the Triennial Review of the HTA
- Strengthen our arrangements for horizon scanning and accessing external expertise, in particular on scientific trends and developments, to better inform policy development and strategic planning
- Actively seek opportunities to reflect and shape thinking on the future of regulation in the health sector
- Continue to upgrade and develop our Customer Relationship Management (CRM) system, website and portal[3] to better meet business needs

3 The portal is a secure section of the HTA's website which allows for the submission of confidential reports and information

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

Our deployment objectives for 2016/17 are:

a) To manage and develop our people in line with the HTA's People Strategy (covered in the Human Resources section below)

b) To ensure the continued financial viability of the HTA while charging fair and transparent licence fees and providing value for money

c) To provide a suitable working environment and effective business technology

During 2016/17, we will:

- Deliver the People Strategy in line with its associated road map, including consulting staff on emerging issues and relative priorities
- Undertake a full review of our licensing fees and consult stakeholders on the setting of licence fees
- Ensure best use of office space to control accommodation costs
- Undertake a re-tendering exercise for our IT support services

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

Resources – people and finances

Our people

Full time equivalents (FTEs)

	Q1	Q2	Q3	Q4
Starting count – payroll	49	49	49	49
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	**49**	**49**	**49**	**49**

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 49, which is supported by our income plans.

Staff turnover (which for the 2014/15 business year was just under 30%) and maternity leave are ongoing issues for the HTA. We have introduced 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 this size. In response to this challenge, the HTA has developed a People Strategy to strengthen our offer to staff. Alongside this, business planning activities for 2016/17 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.

This issue was identified by the Triennial Review team and as a result, we intend to develop a knowledge management system to mitigate against the impact of the loss of key staff, and this will be a priority for 2016/17.

During 2016/17 it is expected that:

- the HTA will have 3.5 FTEs who are classified as very senior managers, within the total of 49 FTEs
- there will be one FTE Human Resources member of staff within the full complement of 49 FTEs
- the training budget will equate to around two per cent of the pay bill
- 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, the Department of Health. We also receive a small amount of income for undertaking activities on behalf of the devolved administrations.

The licence fee income pays for a wide variety of activity 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 2016/17 is shown below:

Income	**£000s**
Department of Health funding	703
Licence fees	3,249
Other income	505
Total income	**4,457**
Expenditure	**£000s**
Operating costs	
Staff costs	2,931
Other operating costs	1,333
Total operating costs	4,264
Capital charges	193
Total revenue expenditure	**4,457**

We have reduced our licence fees since 2010 by making efficiencies that enable us to manage with 38 per cent less income from fees.

Making the most of our resources

The Director of Resources is responsible for overseeing the procurement of goods, services and contracts. HTA policies set out the procurement strategy and governance arrangements, and the HTA uses centralised solutions for spend wherever possible. During 2016/17, it is expected that the HTA will procure for IT services. Any procurement that takes place would follow the necessary frameworks and principles.

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, Innovation and Skills-managed building along with other ALBs. We continue to seek opportunities to gain the greatest value for the space that we have available. At the end of 2015/16, we reduced the space the HTA occupies and extended our arrangement to make available more workstations within the HTA office space to our neighbours, the NHS Litigation Authority.

The HTA's IT strategy is refreshed every year to ensure IT supports the HTA's business and the HTA has outsourced provision of IT services for some years. The present contract has been extended to 2016 while we consider the future arrangements with the Department of Health.

With regards to information governance, the Director of Resources is the Senior Information Risk Owner, and Information Asset Owners are in place. The HTA assesses risk at least annually 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, and these are largely offset by inflation

increases. For 2016/17, we reduced our net costs by reducing the space the HTA occupies and extending our rental agreement with the NHS Litigation Authority, to keep licence fees as low as we can.

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. We ensure 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.

We continue to review our processes to streamline them as much as possible and 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. As part of the consultation stage of the triennial review of the HTA, stakeholders commented positively on the efficiencies achieved in recent years.

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 third sector organisations.

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 collaboration for 2016/17:

- **Review of the HTA's Codes of Practice and Standards:** in 2015 the HTA undertook a comprehensive review of its Codes of Practice and Standards; the first review of its kind since 2009. A public consultation exercise generated 113 responses, and over 300 individuals attended stakeholder engagement events around the country. Subject to Parliamentary approval, the revised Codes and Standards will be published in 2016, with the new Standards to be implemented in 2017. The HTA will provide training on the new Standards throughout 2016/17.
- **Research sector:** with HTA membership of the HRA's Collaboration and Development Forum, we will continue to work closely with the HRA to ensure that those involved in research can be assured of consistency of approach and a high degree of information-sharing between the two organisations. We will also continue to work with the National Research

Ethics Service NRES (now part of the HRA) through our Memorandum of Understanding to ensure that advice and guidance on research regulation is clear, coordinated and consistent, and to ensure that researchers using the 200 HTA-licensed tissue banks continue to benefit from a streamlined process, where Research Ethics Committees give generic approval for tissue collection, storage and release arrangements.

- **Post mortem sector:** we will continue to work closely with the Royal College of Pathologists and other professional stakeholders through our Histopathology Working Group to ensure that our regulation is responsive to the needs of the sector, whilst maintaining public confidence. We will work to develop further the HTA's relationship with Coroners and Coroners' Officers to ensure that human tissue samples are treated in line with the wishes of the family after Coroners' post mortem examinations. We have strong links with the Forensic Pathology Unit of the Home Office and will continue to include samples held under the authority of the Police within the scope of our inspections. We will also continue to collaborate with the United Kingdom Accreditation Service (UKAS), undertaking joint inspections where opportunities are identified.
- **Organ donation and transplantation sector**: we will continue to work with NHS Blood and Transplant (NHSBT) to avoid duplication of reporting or information-gathering to limit the burden on those working in this area
- **Human application sector:** we will continue to deliver joint inspections of the small number of establishments co-regulated with the Medicines and Healthcare products Regulatory Agency (MHRA), including those establishments involved in translational research of regenerative therapies, and deliver joint advice and guidance. We will also explore joint inspections of the five establishments involved in embryonic stem cell research co-regulated by the HTA and the Human Fertilisation and Embryology Authority (HFEA)
- The HTA continues to contribute to the 'One Stop Shop', a partnership between the four life science regulators which enables businesses and other organisations in the life sciences industry to quickly and easily navigate the different regulators and allow them to get the right advice more quickly
- We continue to work with the MHRA to streamline the regulation of Advanced Therapy Medicinal Products (ATMPs). Our aim is to reduce the regulatory burdens on those developing these products without increasing the risk to patient safety

Stakeholder and public involvement

We will review our joint working protocols and Memoranda of Understanding with the MHRA, HRA and the NRES, which 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.

We will continue to seek to identify opportunities to work with public-facing organisations to inform the public about the work of the HTA across the sectors we regulate. In doing so, we will 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. Enhancing our public involvement activities is a priority for 2016/17, and will commence with the launch of a public-facing summary of our Codes of Practice and guiding principles.

The HTA's Stakeholder Group continues to provide valuable insight and advice on a range of regulatory issues following its formation in 2013. 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.

Europe

We are the Competent Authority for the EU Directive on the quality and safety of tissues and cells used in human application. We will be working on the following projects in relation to this role during 2016/17:

- the implementation of new EU legislation on coding for tissue products, which will improve traceability of products
- the implementation of new EU legislation on the import of tissues and cells into the EU
- the development of guidance for novel therapies
- the establishment of a framework for joint inspections between Member States and in third countries, when a need for such inspections is identified

In addition to the above projects, we are working with the European Commission and a small number of other Member States to develop proposals for improving collaboration between Competent Authorities, with different but linked areas of competence, such as Blood and Medicines. This work is

intended to address some of the regulatory issues arising from the emerging regenerative and ATMP sector.

Staff and shared services

The HTA has some strong collaborative links with other ALBs with regard to staffing, and shares its Director of Resources and Head of Finance with the HFEA. There are more informal links in place with other ALBs and the Department of Health to share expertise and good practice, and the HTA uses 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 needs.

Representation

The HTA plays an active role in a number of groups and committees in order to share the experience and knowledge we have gained through ten years of regulation. These include the Government's Regenerative Medicine Expert Group, NHSBT's 2020 Strategy Oversight Group, the Home Office's Forensic Pathology Specialist Group and the Health Research Authority's Collaboration and Development Forum. We also provide advice and guidance to organisations and individuals on an ad-hoc basis.

The Shared Delivery Plan

The HTA is committed to supporting the delivery of the strategic aims set out in the Department of Health's Shared Delivery Plan. Although, as a regulator, the HTA is one step removed from patient care and the delivery of front-line services, we contribute directly to a number of the Plan's objectives.

Securing high quality health and care services

The HTA is responsible for ensuring the quality and safety of tissues and cells for human application and organs for transplantation, contributing to the provision of a high standard of care for patients requiring these interventions, and to successful clinical outcomes. Ensuring public and professional confidence requires us to protect the foundations on which that confidence is built, and we believe that it is maintained if the core principles outlined within the Human Tissue Act are adhered to. These principles are:

- **Consent** and the wishes of the donor, or where appropriate, their nominated representatives or relatives, have primacy when removing, storing and using human tissue;
- **Dignity** should be paramount in the treatment of human tissue and bodies;
- **Quality** should underpin the management of human tissue and bodies;

- **Honesty** and openness should be the foundation of communications in matters pertaining to the use of human tissue and bodies.

Applying these principles reduces the risk of harms, such as the transmission of disease in organ transplantation, compromised patient safety where tissue is used for human application, or distress to the families of the deceased. All of these harms have the potential to damage public confidence, and as such, these principles underpin the HTA's regulatory framework.

We continue to work to supporting our regulated sectors' efforts to engage with the public, and ensure that there are no regulatory barriers to the donation and use of tissue and organs for research into conditions such as dementia.

Our work in the post mortem sector gives primacy to the dignity of the deceased, ensuring that the standard of care that they receive reflects that given in life. In 2015, the HTA published a report into mortuary capacity and is working with a range of organisations to implement the recommendations made in this report.

The HTA is part of the value chain in a number of areas of healthcare, including living and deceased organ donation, the use of tissues and cells for human application, and care after death. By ensuring that we are an effective and efficient organisation, we add to the resilience of the healthcare system, never forgetting our key role in ensuring the safe and ethical use of human tissue and the importance of valid consent.

Empowered patients, citizens and communities

The HTA was established to protect the right of an individual to consent to the removal, storage and use of human tissue and organs for post mortems, research, anatomical examination and public display. We also have a role in protecting living organ donors. We provide information to patients and the public about what they should expect from the services we regulate.

Delivering efficiency and productivity improvements

Through a focus on continuous improvement and right-touch regulation, the HTA aims to ensure that regulatory burden is kept to a minimum. We maintain an ongoing commitment to reviewing and revising our policies and procedures and work closely with partner organisations to seek ways of improving the experience of regulation for our licence holders.

The HTA ensures value for money for taxpayers by ensuring that we deliver high-quality, right-touch regulation, while keeping costs proportionate. The focus on streamlining and increasing efficiency from 2010 to the present

day has made the HTA a lean organisation, delivering a wide range of highly effective functions with just 49 FTE staff.

Year-on-year, the HTA sets itself stretching targets to make sure that our performance improves in ways which benefit those we serve, whether this is through a reduction in the time it takes for a living organ donation case to be assessed, or how quickly we respond to enquiries. As an organisation, we are clear about our aims and objectives, and work together with colleagues at the Department of Health and other Arm's Length Bodies (ALBs) to reach and exceed these targets.

Aspects of these themes can be seen throughout our work within the sectors we regulate, through our role in organ donation and transplantation, in the use of tissue for human application, our oversight of post mortem services, our work in the research sector, or how we govern our organisation. We have developed effective partnerships which inform our regulatory processes and actively engage with stakeholders and clinicians, providing advice and guidance on all issues within our remit.

Supporting Innovation and Growth

The HTA maintains an agile regulatory framework and works collaboratively with other regulators to ensure easy navigation of the regulatory environment for researchers and others involved in health innovations which use human organs, tissue and cells. In line with government requirements, we have set out our plans to support innovation on page below (pages 20 to 22).

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 Regulation

Many establishments licenced by the HTA work at the cutting edge of science, and it is our commitment to ensure that we deliver a regulatory package which promotes innovation and development whilst protecting the public. For the 2016/17 business year, Her Majesty's Treasury requires that all regulators produce a plan to outline their approach to stimulating and supporting innovation, both within their organisations, and in the regulated environment. Using the three key themes set by the Department for Business, Innovation and Skills below, we have set out our anticipated activities for 2016/17.

How legislation and enforcement frameworks could adapt to new technologies and disruptive business models to encourage growth

The emergence of new technologies continues to shape the regulatory landscape, presenting new opportunities for regulators and the regulated alike. 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 within the scope of the Human Tissue Act.

The HTA has a strong track record of providing free advice and guidance to all enquirers as required under our legislation. Enquiries are answered by staff involved in inspection and regulation who are equipped to give responses. The HTA will undertake a review of its enquiries service in 2016/17 to establish whether this service can be delivered with greater efficiency. The HTA received around 2000 enquiries in 2014/15.

We have an established track record of working collaboratively with other Regulators to clarify remit, particularly with novel therapy development (we have published position statements with MHRA, HFEA, and we work closely with HRA).

There is well-established collaboration between HTA and HRA for relevant enquiries relating to human tissue research under the Human Tissue Act 2004 and these arrangements are kept under review through regular joint meetings. With regard to continuously improving the help available to researchers working within the wider research regulatory environment, the HTA will continue to work with the HRA through its long-standing Memorandum of Understanding and information-sharing agreement. Both organisations are currently developing improved joint guidance for researchers and have recently agreed to the secondment of a member of HTA staff to further support the

development of the areas of human tissue regulation where the remits of both bodies adjoin.

Alongside this, the HTA plays a key role in the Regulatory Advice Service for Regenerative Medicine. This 'one stop shop' provides support to researchers and manufacturers of advanced therapy medicinal products (ATMPs). The service was launched in October 2014, and is hosted by the MHRA Innovation Office, with the management and governance of the service led by the HTA. The HTA is currently exploring the possibility of extending the service to all researchers, not just those working on ATMPs.

The HTA maintains a log of potential amendments to the Human Tissue Act that could benefit our stakeholders, and although we have been advised that there are no current plans for legislative change in this area, we understand that this is an area that the Department is keeping under review. Where we identify opportunities to deliver benefits that do not require legislative change, we will seek to implement such improvements.

An assessment of how new technology is likely to shape the sectors being regulated

The drive to reduce animals and their tissues in research, in favour of more predictive research using human tissue, means that HTA is continuing to play a role in supporting greater access to high quality human tissue. This is being done in partnership with researchers, other regulatory bodies and the National Centre for the Replacement, Refinement and Reduction of Animals in Research (NC3Rs).

The HT Act and regulatory framework put in place by the HTA have permitted and supported the use of donated human material for realistic surgical training, providing surgeons with lifelike opportunities to practise procedures without posing any risks to patients. The demand for such training has driven the wider adoption of newer embalming techniques and the greater use of unembalmed, fresh-frozen material. By staying in touch with the evolving profile of this sector, the HTA will continue to support, guide and regulate it appropriately.

We recognise that the growing use of genomics in research relies on human tissue as the starting point. Our role in regulating consent means that we will continue to provide up-to-date guidance and on-going public confidence that donated material is stored and used appropriately.

In the post-mortem sector, the use of post-mortem cross-sectional imaging (PMCSI), which includes post mortem computed tomography (PMCT) and post mortem magnetic resonance (PMMR), may be used instead of or as an adjunct to post-mortem examination to determine the cause of death. PMSCI

provides a three-dimensional image of the patient's internal organs and structures and soft tissues of the body without the need for dissection, and therefore its use is expected to increase in the years ahead. The HTA does not, at present, consider PMCSI to fall within the scope of 'the making of a post-mortem examination' for the purposes of licensing under the HT Act.

The HTA is in regular contact with leaders in the field of PMSCI and has contributed to major papers ensuring that regulatory requirements are reflected and understood. We will continue to monitor developments in this field.

Actions for how regulators could better utilise new technologies to generate efficiency savings and reduce burdens on business.

We are exploring how to better use the HTA's online portal to disseminate and receive information for licensed establishments. We are due to launch a system which will allow licence certificates to be accessed via a secure online log in, reducing the time and effort required to issue certificates, and to enable establishments to better access information.

Annex A

Baseline Business Plan 2016/17 – Deliverables

Key Performance Indicators (KPIs)

Reference number	Detailed business activity	Performance Indicators
Delivery KPI 1	To undertake a risk-based inspection/ audit programme	At least 180 site visits to take place during the business year across all sectors
Delivery KPI 2	To seek feedback from establishments after each inspection and analyse and report the results each quarter	At least 80% of responding establishments agree with the post-inspection survey question, 'Has the inspection/audit process helped improve the ways in which your organisation works?'
Delivery KPI 3	To take appropriate action for all regulatory non-compliances	100% of Corrective and Preventive Actions (CAPAs) implemented to address major shortfalls are completed to the HTA's satisfaction within agreed timescales or further regulatory action is implemented
Delivery KPI 4	To make appropriately evidenced decisions to agreed quality standards	100% of non-panel cases turned around within five working days. Average to be reported monthly
Delivery KPI 5	To make appropriately evidenced decisions to agreed quality standards	100% of panel cases turned around within ten working days. Average to be reported monthly
Delivery KPI 6	To answer enquiries in a timely and accurate way	At least 95% of enquiries are answered within ten working days of receipt, excluding body donation enquiries
Development KPI 1	To undertake a review of the HTA fee structure and set fee levels for 2017/18	Fee structure in place, following necessary consultation and communication, by December 2016

Reference number	Detailed business activity	Performance Indicators
Development KPI 2	To deliver a project to implement the EU Directives on Coding and Import/Export	EU Directives on Coding and Import/ Export implementation project red-amber-green (RAG) rating to remain green or amber during the course of the project
Development KPI 3	To deliver a project to successfully release the HTA's revised Codes of Practice	HTA's Codes project RAG status to remain green or amber during the course of the project
Development KPI 4	To deliver a project to implement the HTA's revised Standards	HTA Standards project RAG status to remain green or amber during the course of the project
Development KPI 5	To develop a plan for Designated Individual (DI) relationship development	Plan in place during 2016/17
Deployment KPI 1	To reduce attrition rates through improved selection and targeted measures to retain staff	Attrition rate measured monthly on a rolling annual basis, with risk to be monitored
Deployment KPI 2	To maintain 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, with risk to be monitored
Deployment KPI 3	To maintain organisational capacity and capability	Number of vacancies reported monthly, with risk to be monitored
Deployment KPI 4	To 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
Deployment KPI 5	To undertake a review of the HTA salary bands to assess market relativity	Review completed and outcome reported to the HTA Remuneration Committee by the end of May 2016
Deployment KPI 6	To provide access to structured leadership development training programs	A structured approach to leadership development is in place and accessible to staff during 2016/17

Performance Indicators (PIs)

Reference number	Detailed business activity	Performance Indicators
Delivery PI	Effectively show progress against the HTA's triennial review recommendations	Develop and publish an action plan against each of the triennial review recommendations
Delivery PI	To process licence applications and variations in accordance with standard operating procedures (SOPs)	At least 90% of completed applications to vary a licence are processed within 20 working days of receipt
Delivery PI	To 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
Delivery PI	To deliver annual panel training to Authority Members	All Authority Members undertake panel training in 2016
Delivery PI	To update our Memorandum of Understanding documents as and when required, and continue sharing data	All Memoranda of Understanding are updated and published within the business year
Delivery PI	To fulfil the role specified for the Governance and Quality Manager in the HTA's Freedom of Information governance documents and respond to all requests in accordance with the Freedom of Information and Data Protection Acts	All requests under the Freedom of Information Act responded to within 20 working days; all requests under the Data Protection Act responded to within 40 calendar days, where this applies. For all responses to be published within five working days of issue.
Delivery PI	To manage all HTA phone and email enquiries	Enquiries are answered or assigned to the appropriate person to manage within 24 hours of receipt
Delivery PI	To publish a regular Feedback Report to the Senior Management Team and the Authority, and DH on request	All complaints are acknowledged within three working days and investigated and responded to within 20 working days
Delivery PI	To scope the requirements for compliance updates for all sectors regulated under the HT Act and ODT in preparation for 2017/18	Delivery of a project plan outlining the requirements for future compliance updates

Reference number	Detailed business activity	Performance Indicators
Delivery PI	To organise the HTA's annual review event and produce the annual review publication	To deliver the annual review event on 12 July 2016 and report on stakeholder feedback on the event
Delivery PI	To share learning gained from SAEARs reports received in the human application sector.	Development of a strategy for dissemination of learning in human application SAEARs by Q4
Delivery PI	To issue draft inspection reports within agreed timeframes	At least 90% of draft inspection/audit reports are sent to the DI/licence holder for an accuracy check within 20 working days of the end of the inspection/audit
Delivery PI	To share learning gained from HTARI reports received in 2014/15 and 2015/16	Publication of a summary report on HTARIs in Q1
Delivery PI	To seek feedback from establishments after each inspection and analyse and report the results each quarter	At least 80% of responding establishments rate the overall inspection process as either good or excellent
Delivery PI	To take appropriate action for all regulatory non-compliance	100% of audited corrective and preventive action plans have sufficient evidence provided to ensure that the shortfall has been addressed
Delivery PI	To ensure the quality of reports submitted by Independent Assessors (IAs)	90% of Independent Assessor reports are fit for purpose on submission
Delivery PI	To exploit digital communications as a vital HTA communications tool	Digital (website and newsletter) survey takes place in Feb/March 2017. 80% of all those responding say that they find the website easy to use and the content useful
Delivery PI	To complete annual Independent Assessor re-accreditation	Independent Assessor re-accreditation completed in March 2017
Delivery PI	To ensure that the assisted functions provided by NHSBT continue to deliver value for our stakeholders.	Comprehensive review of NHSBT SLA in Q2.

Reference number	Detailed business activity	Performance Indicators
Delivery PI	To finalise inspection reports and publish them on the HTA website within agreed timeframes.	At least 90% of inspection reports are finalised and published on the HTA website within 10 weeks of the end of the inspection.
Development PI	Develop plans and respond effectively to the burden reduction, innovation and regulation plan, and regulation review	Meet all deadlines for submission of responses and plans. Submissions to be of an acceptable quality. Plans implemented as stated
Development PI	To strengthen the HTA's formal arrangements for policy development	For a structured policy function to be established by end Q2, and rolled out by the end Q3
Development PI	To develop e-learning materials for DIs (proof of concept and initial materials delivered as part of the implementation of the new licensing Standards)	Project RAG status to remain green or amber during the course of the project
Development PI	To introduce a revised Representations process	Project RAG status to remain green or amber during the course of the project
Development PI	To explore whether there is further scope for the introduction of reduced-resource inspections under the HT Act	Project scoping complete during 2016/17
Development PI	To ensure quality enquiry responses are sent and develop a database of enquiry responses	Survey conducted before end of April 2016 and database created, with early feedback sought
Development PI	Establish appropriate knowledge management and horizon scanning functions for the HTA	Project RAG status to remain green or amber during the course of the project
Development PI	To maintain a record of areas for legislative and policy review which could potentially reduce burden	Project RAG status to remain green or amber during the course of the project
Development PI	To develop a plan for audit of licensing decisions	Delivery of an audit plan to quality assure licensing decisions by December 2016

Reference number	Detailed business activity	Performance Indicators
Development PI	To routinely review data from inspections and internal feedback to inform our risk-based approach and share learning with establishments	Project scoping complete during 2016/17
Development PI	To produce a policy on the use of Directions and legal notices	Project RAG status to remain green or amber during the course of the project
Development PI	Identify opportunities for increased joint working with other regulators and accreditation bodies to facilitate a reduction in burden for licensed establishments	Produce and end of year report on progress against Triennial Review recommendations
Development PI	Complete NHSLA relocation and consider office restructuring to provide meeting room space	NHSLA area tidy and the office suits HTA's needs.
Development PI	To ensure the security of HTA information assets through compliance and awareness	Zero data security incidents. Data Protection Registration renewed annually. Staff inductions and annual refresher training
Development PI	To ensure HTA uses a vendor supported finance system	Upgraded to new version and future compatibility with CRM
Deployment PI	To form a working group to review options and develop a reward and recognition programme	Recommendation put forward to HTA Remuneration Committee by autumn 2016
Deployment PI	To provide opportunities for Authority Members and HTA staff to interact	Staff report a greater level of understanding and interaction with Authority Members
Deployment PI	To review the HTA competency framework	To undertake a review of HTA competency framework and ensure it is fit for purpose
Deployment PI	To review the HTA induction process	To undertake a review of the HTA induction process
Deployment PI	To advise on and provide reliable IT that supports effective working and implements the IT strategy	No unplanned outages

Reference number	Detailed business activity	Performance Indicators
Deployment PI	Provide operational support to all HTA colleagues	All travel and accommodation is booked six weeks prior to the date of travel where possible
Deployment PI	To manage IT contracts and maintain adequate contract arrangements with key suppliers including: BCC, WebCurl and BBD	Supplier assurances including the standard assurance template. A smooth transition to, and satisfaction with, new IT contract(s) for IT services and portal
Deployment PI	To maintain acceptable levels of internal audit recommendation i.e. low-medium	90% of audit recommendations are either medium or low in severity
Deployment PI	To pay all suppliers within ten working days in accordance with Government's Best Payment Practice (BPP) code	90% of payments made within ten days of receipt of undisputed invoice
Deployment PI	To manage the HTA's finances to ensure sufficient funds are in place to meet payments required/appropriate spending	90% of licence fees received within 56 days of invoicing
Deployment PI	To ensure all existing policies meet the needs of the HTA and are up to date with good practice and current legislation	Current policies are reviewed in line with expiry dates and new ones implemented in time for external change requirements
Deployment PI	To monitor equal opportunities data and develop systems to capture required information	The HTA has a diverse workforce, as evaluated by regular equal opportunities reports, which are to be produced on an annual basis. Equal pay audit to be carried out in Q3
Deployment PI	To undertake a staff survey and develop an action plan in response to key issues raised	2016-17 staff survey to be conducted in May 2016
Deployment PI	Annual Information Asset housekeeping	Affected assets cleared and audit trail complete
Deployment PI	To clean and improve the Sharepoint system by looking at how it can support other business areas	Sharepoint system clean and improvement project RAG status remains amber or green during the course of the project.

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