

2009/10 Business plan

The HTA Strategic Plan for 2008/09 – 2013/14 is available here:

http://www.hta.gov.uk/db/documents/2008-04-21_strategic_plan_2008_09_2013_14_published_on_website.pdf

Implement human tissue legislation in a way that promotes safe and ethical practice and is conducted in accordance with the wishes of the individual.		
Objective	2009/10 high level activity	Business plan activity to be measured
1. Interpret and implement the principles embodied in the HT Act, EUTCD, and any future relevant European legislation.	Apply all appropriate licensing, inspection, enforcement and regulatory tools to ensure establishments are licensed in accordance with domestic and European legislation.	Implement a risk based schedule of inspections.
		Improved collection and analysis of data in risk matrices will ensure that risk assessments reflect the risk of non-compliance at each licensed establishment and are used to target our regulatory and inspection resource.
1. Interpret and implement the principles embodied in the HT Act, EUTCD, and any future relevant European legislation.	Apply all appropriate licensing, inspection, enforcement and regulatory tools to ensure establishments are licensed in accordance with domestic and European legislation.	Apply regulatory enforcement policy.
	Convert relevant establishments to a continuous licensing system using a phased approach that can be effectively resourced.	Vary relevant licences using a risk based; proportionate approach, only seeking information that is essential prior to conversion.

	Seek to influence the shape and direction of the EU Organ Donation Directive.	Actively contribute to negotiating strategy to ensure Organ Directive is proportionate and workable.
		Contribute to the negotiations to remove licensing transplantation and/or procurement from the Directive.
	Prepare for implementation of the EU Organ Donation Directive.	Contribute to the negotiations to ensure the Organ Directive is congruent with current HTA licensing processes.
Implement human tissue legislation in a way that promotes safe and ethical practice and is conducted in accordance with the wishes of the individual.		
Objective	2009/10 high level activity	Business plan activity to be measured
1. Interpret and implement the principles embodied in the HT Act, EUTCD, and any future relevant European legislation.	Regulate living organ donation.	Reaccreditation of all IA and AA.
		Review operation of the approvals system, including the panel system, and recommend any improvements.
		Contribute to the Programme Delivery Board on the Organ Donation Task Force recommendations.
	Contribute to the development of government policy on organ transplantation and the regulation of the use of human tissue.	
	Ensure that the HTA plays a leading role in the review of the Human Tissue Act.	Develop a programme plan for review of the Human Tissue Act.

2. Ensure that the wishes of the individual are respected.	Ensure that the consent requirements of the HT Act are applied consistently and in accordance with the codes of practice.	Review consent in relation to the Organ Donor Register.
		Work with DH to improve the harmonisation of the consent process.
3. Raise and maintain standards to ensure that tissue and cells are safe to use in transplants.	Provide advice and guidance using a variety of media to enhance compliance with statutory requirements, HTA standards and codes of practice.	Analyse data from 2008/09 inspections of the human application sector and publish summary inspection report to share learning and raise standards.
		Develop a project initiation document and project plan to deliver a quality conference for the Human Application sector in Q1 of 2010/11 business year.
	Develop and embed processes arising from European Union Tissue and Cells Directive (EUTCD).	HTA participation at relevant EC led meetings to influence the strategic direction of how the EUTCD is implemented.
4. Raise and maintain standards to ensure that tissue and cells provide the best possible basis for research, education and training and other scheduled purposes.	Provide advice and guidance using a variety of media to enhance compliance with statutory requirements, HTA standards and codes of practice.	Analyse data from 2008/09 inspections of the post mortem (PM) sector and publish summary inspection report to share learning and raise standards.
	Ensure that there is adequate stakeholder compliance and understanding.	Embed the new codes of practice into the inspection process.
		Deliver a professionally presented,

		informative and developmental conference for Designated Individuals and others working in the post mortem sector.
Play a leading role in the development of the regulation of human tissue.		
Objective	2009/10 high level activity	Business plan activity to be measured
5. Play a leading role in helping stakeholders understand and implement legislation.	Issue revised codes and other guidance.	Liaison with devolved assemblies and DH lawyers to finalise codes for laying before Parliament.
		Prepare rationale during Q1.
		Edit and design the codes of practice for laying before Parliament.
		Produce web version of codes and launch eight revised codes in appropriate format on website by September 2009.
		Update the Living donor transplantation: Guidance for transplant teams and Independent Assessors.
	Test stakeholder understanding and engagement.	Issues identified in workshop with private sector bodies informs report to Authority and 2010/11 business plan.
	Initiate and contribute to debate and share lessons learnt.	Facilitate Cord Blood Debate
6. Anticipate future changes in the field of human tissue use.	Work with stakeholders to identify scientific, medical and other developments that may impact on the	Engage Authority members on horizon scanning.

	HTA and its stakeholders.	
		Engage leading thinkers in the wider health and regulatory community.
		Horizon scanning to identify developments in stem cell and cord blood research/use.
7. Work in collaboration with other regulators, professional bodies, competent authorities and the European Commission.	Work with and influence European Commission to develop the role of Competent Authorities.	New developments are documented and fed into 2010/11 business plan.
	Horizon scan for areas of regulatory overlap, gaps and develop Memoranda of Understanding with other regulators where appropriate.	Engage with other key regulatory bodies to develop MOUs, particularly with respect to regulating ATMPs.
Maintain the confidence of the public and professionals and continue to work in partnership with them.		
Objective	2009/10 high level activity	Business plan activity to be measured
8. Operate our regulatory framework in a way that gives confidence to professionals and the public.	Work with internal and external stakeholders and other regulators to ensure clarity of roles and strategic purpose.	Review and refine communications strategy.
		Review and refine media strategy.
		Ensure appropriate public accountability.
		Contribute to Organ Donation Taskforce programme delivery board, and donation ethics and stakeholder communications strategy groups.

		Produce action plan to implement Hampton Implementation Review recommendations and incorporate into 2009/10 business plan.
	Continue to build and maintain relationships with new and existing stakeholders.	Ensure appropriate professional accountability.
8. Operate our regulatory framework in a way that gives confidence to professionals and the public.	Work with internal and external stakeholders and other regulators to ensure clarity of roles and strategic purpose.	Review stakeholders in patient groups, private and other 'cross-cutting' sectors and develop a programme for engagement.
		Develop and implement Parliamentary affairs programme.
8. Operate our regulatory framework in a way that gives confidence to professionals and the public.	Evaluate the impact human tissue legislation on our stakeholders.	Create better understanding of the impact of HT legislation and regulation on the research community and communicate findings to sector and DH.
	Work with the Royal College of Pathologists, Coroners Society, Department of Health, Ministry of Justice to influence improvements in existing and new legislation relating to coroners.	Work with MOJ to influence the Coroners and Justice Bill.
9. Engage, consult, communicate and work with our stakeholders to help refine our advice and guidance, standards and regulatory methods.	Improve and refine our communications materials and routes.	Conduct audit of HTA communication activities, advice and guidance meetings and events to inform comms strategy and produce quality audit report informing new communications strategy and future

		direction.
Be recognised as an organisation that makes the best use of the knowledge and information it holds.		
Objective	2009/10 high level activity	Business plan activity to be measured
10. Make best use of knowledge and quality management systems and processes and provide a responsive service to internal and external stakeholders.	Review and refine our Information Management Platform and Communications Tool (IMPACT).	Improve data quality for internal and external use.
		Review and, if appropriate implement HTA wide quality assurance process.
		Revise and update HTA quality manual to make it appropriate for IMPACT.
		Conduct audit of organisational policies and procedures in each directorate.
		Launch HTA intranet implementing recommendations of internal communications strategy.
		New enquiries log and system fully developed and all staff trained to use it.
		Review and improve procedures for handling complaints by reviewing complaints register.
	Embed the new system for managing enquiries to ensure accurate, consistent and timely guidance and responses.	Conduct audit of types of enquires to inform development of FAQs and lines to take and management reporting in Q2.
		Improve responsiveness and accuracy of enquiries.

	Review and refine website.	Launch 'refreshed' HTA website with up-to-date information in top-level web pages.
		Guidance for updating website approved and implemented, with all secondary web pages having allocated staff responsible for updating.
		Audit best practice for e-newsletters in Q2.
	Develop three year strategy for licensing, enforcement, investigations and inspections.	Develop a system to make licensing, enforcement, investigation and inspection activity publicly available on the website in 2010/11.
Be recognised as an organisation that makes the best use of the knowledge and information it holds.		
Objective	2009/10 high level activity	Business plan activity to be measured
		Introduce CRM
		Review and Updating of Guidance
Be recognised as an organisation that makes the best use of the knowledge and information it holds.		
Objective	2009/10 high level activity	Business plan activity to be measured
		Publish complaints and whistle blowing guidance about licensed establishments.
		Information received as the result of whistleblowers, complaints, serious adverse events/reactions and investigations will be analysed so that trends and repeated issues can be used to improve standards at licensed premises. The timeliness and

		consistency of HTA responses to whistleblowers and complaints will also be evaluated and monitored. Information will be used operationally to transfer knowledge between regulatory staff.
		Review and revise Audit Committee terms of reference.
		Evaluate public and professional stakeholder opinion.
11. Ensure we identify and anticipate strategic and operational risks.	Implement new risk management strategy.	Develop new risk register that links key strategic risks (Authority level) with operational risks (directorate).
		Work with the Authority to review HTA strategic objectives.
Ensure that the HTA is a distinctive dynamic organisation that people want to work for.		
Objective	2009/10 high level activity	Business plan activity to be measured
12. Deliver a learning and development programme that helps us achieve our demanding goals.	Implement a learning and development programme for all staff.	Deliver a programme of in-house generic inspector training for regulation staff.
	Proactively manage organisational change.	Heads of Regulation identify specific 'extra' training needs and ensure delivery of appropriate training.
	Support the Authority in improving corporate governance.	Develop and deliver a governance development plan for the Authority.
13. Create an organisation with a strong corporate culture.	Implement the HTA's HR strategy.	Complete values exercise with staff and Authority and establish baseline for

		awareness.
	Implement internal communications strategy.	Annual survey of employee engagement.
Continue to apply the principles of better regulation and provide value for money for the taxpayer and licence fee payer.		
Objective	2009/10 high level activity	Business plan activity to be measured
14. Find the most economical, efficient and effective ways of delivering the service.	Grow the business to its proper size to meet the regulatory need.	Plan the move to new offices in 2010/11.
		Review scope for hot desking and home working.
		All 25 additional posts recruited with no re-advertising needed.
		Review and refine fee structure.
		Hold at least two workshops on fees structure.
		Launch consultation.
	Ensure the delivery of effective and robust internal support to the organisation within a framework of financial discipline.	Deliver 9 month 'Hard Closing' of accounts.
		Deliver year end closing to IFRS standards.
		Annual Report and Accounts published in Q1.

	Implement new licensing and inspection IT platform.	Existing 13 systems mapped and documented.
		Specification and invitation to tender to consultants prepared.
		Delivery of the first phase discovery and design.
		Launch calendar for HTA and Authority events, inspections and external meetings in CRM.
		Publish 'lines to take' section in CRM.
14. Find the most economical, efficient and effective ways of delivering the service.	Implement new licensing and inspection IT platform.	Run LMS / enquiries / contacts database in parallel with CRM (Q4).
		Fully implement CRM, with full LMS, enquiries, contacts and calendar functionality – as identified in the project requirements document.
		Comply with DH Gateway requirements by submitting our national communications to Gateway for approval.