

HTA Chief Executive's business plan and communications report 1 August – 31 August 2008

Business objective	Milestones	Progress over the month
A. Better regulation and legislation – strategic, proportionate and rigorous		
1. Legislative changes have been identified and considered in a timely fashion, are reflective of the wishes of stakeholders and the public and comply with our principles of ethical and safe practice.	Agree policy with Department of Health (DH) on implementation of Organ Donation Taskforce (ODTF) report recommendations on transplantation, coroners etc (Q1)	Executive contributing to DH programme delivery board. Shaun Griffin attended communications strategy group meeting on 6 August. Peter Lemmey has been asked to sit on the Donation Ethics Committee Project Group, set up to scope the role and terms of reference for the Donation Ethics Committee recommended in the ODTF report.
	Hold workshop with DH and other agencies on European Commission (EC) Donation Directive and implications for competent authorities (Q2)	Paper on key points on the current working papers on the Donation Directive drafted and shared with DH.
	Agree Authority statement on presumed consent (Q3)	HTA Chair continues to be a member of ODTF on presumed consent and attended last meeting of the ODTF.
2. Work with stakeholders and other organisations further to develop a proportionate regulatory approach that is in keeping with Better Regulation principles.	Hold two workshops to develop licence renewal methodology 2009/10 in each of Qs 1-3	Workshop scheduled for 3 December 2008 for the post-mortem and research sectors. Consultation email sent to Designated Individuals (DIs) in the research sector.
	Prepare for Hampton Implementation Review (Q4)	First draft of self assessment discussed in the Regulation Members Group (RMG) on 19 August. Start up meeting for the Hampton Implementation Review Inspection of HTA was held with representatives of Better Regulation Executive and Bentley Jennison (HTA internal auditors).
3. Ensure that we meet our required duties and obligations as set out by the HT Act and the EUTCD; and that the regulatory framework evolves to reflect legislative requirements, regulatory experience and feedback.	Submit annual report of serious adverse events and reactions to the EC (Q2)	Completed.
	Prepare three year report of all activities at tissue establishments and associated inspection and control measures for submission to the EC (Q4)	
	Revised codes of practice complete passage through Parliament (Q4)	Codes of practice revision programme on target.
		Meeting held with NHS Blood and Transplant (NHSBT) and DH to consider the Authority's proposals for directed deceased donation and the practical implications. Resultant draft policy framework produced and circulated to DH and NHSBT for comment.
		Policy on the sale of human bodies, body parts and tissue agreed by the Emerging Regulatory Policies Programme Board (ERPPB) and finalised.

B. Better communication and consultation – engaged stakeholders and an informed population		
4. All relevant stakeholders are identified and relationships developed in the interests of fulfilling legislative requirements	Hold or contribute to three opinion leader meetings in each of Qs 1-4	Meetings held with NHSBT Chief Executive on 6 August, Medical Research Council (MRC) Chief Executive on 12 August, and Chair of the Association of Anatomical Pathology Technology (AAPT) on 26 August. Meetings arranged with Cancer Research UK, Wellcome Trust and Royal College of Pathologists in September.
5. Major existing stakeholder relationships are reviewed	Complete survey of impact of the HT Act on the research community (Q3)	
6. The sharing of good practice amongst stakeholders and the HTA is undertaken through effective knowledge-sharing and mutual problem-solving	Hold conference for Independent Assessors (IAs; Q3)	Draft agenda agreed. 61 delegates have confirmed attendance.
		Reviewed and provided comments on a guidance document produced by the International Stem Cell Initiative.
		International teleconference held to present HTA's regulatory framework.
7. We continue to raise awareness and understanding about the work of the Authority amongst professionals (individuals and bodies) and our public	Key messages guide produced (Q1)	Key messages guide completed. This will be launched at the report-back event on 18 September.
	Publish Annual Review, Annual Report and Accounts (Q2)	Completed.
	Hold annual report-back meeting (Q2)	Agenda and speakers for the report-back meeting finalised. Confirmation letters issued to attendees. The event will take place at the Wellcome Collection Conference Centre on 18 September.
		Italian law student writing a thesis on DNA Biobanks and their regulation attended HTA for work experience.
8. Consult effectively on codes of practice and a revised fee structure	Prepare final pre-consultation set of revised codes of practice (Q1)	Consultation on revised codes of practice commenced on 1 August.
	Complete series of consultation workshops on revised codes of practice (Q2)	Two workshops will be held in Newcastle on 16 October and two in London on 22 October. The workshops will focus on the research, disposal, post-mortem and consent codes. Invitee lists for the workshops have been finalised.
	Conclude consultation on codes of practice (Q3)	Consultation launched and ongoing.
	Complete review of fee strategy (Q2)	Review of fees project underway, including revision of budget detail.
	Consult on fee strategy (Q3)	Draft consultation letter and communications plan for fees consultation produced.
9. Targeted sector-specific communications are developed	Complete website review incorporating sector-specific sections (Q2)	Project initiation meeting held for website refresh project. A workshop for HTA stakeholders will be held on 23 September. Body donation page on the website updated with regulation assistant contact details.
10. We comply with DH Gateway requirements by submitting our national communications to Gateway for approval.		No communications submitted to DH Gateway during this month.

C. Better Implementation – effective licensing, inspections and regulation		
11. Appropriate advice and guidance is provided to all sectors covered by the legislation.	Hold one Designated Individual (DI) training workshop in each of Qs 2 and 3	Q2 workshop deferred to focus resources on phase 1 inspections of procurement organisations.
		HTA e-newsletter issued on 12 August. Policy on licensing the procurement of vessels during organ retrieval disseminated via e-newsletter. Teleconference held with chairs of the Liver and Pancreas Advisory Groups of NHSBT to brief about the licensing requirements for the procurement of vessels.
12. A new regulation methodology for licence renewals is developed for implementation in 2010.		Workshop to engage stakeholders from the post-mortem and research sectors scheduled for 3 December. Consultation email sent to DIs in the research sector.
13. Sector-specific regulatory strategies are implemented.	Complete sector-specific regulatory strategies (Q1)	Regulatory strategy for research discussed at the RMG on 19 August. Regulatory strategies for post-mortem, human application and anatomy already finalised.
	Fully implement Quality and Safety Regulations (Q2)	
	Complete Independent Assessor (IA) re-accreditation (Q4)	Completed. Reaccreditation letters and guidance on revised reaccreditation process for future years sent out.
14. Facilitate compliance with legislation through a risk-based programme of inspections.	Prepare summary report of 2007/08 inspection findings (Q1)	These reports were discussed at the RMG on 14 July and they will be launched at the report-back event on 18 September. Five Summary Inspection Reports have been sent to Communications for design phase. The reports will be launched at the 18 September report-back meeting.
	Conduct 120 phase 2 inspections in Qs 1-4	Phase two inspection suspended for Q2; however, one phase 2 inspection completed.
	Complete all phase 1 inspections of new licence applications for procurement organisations due to be received by 5 July (Q2)	Five phase 1 inspections completed and associated licence offers issued.
	Complete all phase 1 inspections of new licence applications for organisations applying for licences under the HT Act	One phase 1 inspection completed and associated licence offer issued. One substantive licence issued.

15. Manage the live organ and bone marrow transplant approval programme (with increased numbers).		Transplant approvals: – Five Accredited Assessor (AA) reports received and four approved – 90 Independent Assessor (IA) reports received and 88 approved – One case referred to panel for decision, involving a non-directed altruistic case
16. Non-compliance issues are rigorously addressed through a range of actions including, where necessary, enforcement.		IA and AA bulletins sent out.
	Monitoring and enforcement of DI training (Qs 2-4)	Two Regulatory Action Panels (RAPs) held in August. One resulted in issuing Special Directions. The other RAP was suspended to allow the DI the opportunity to take action and provide additional information. Regulatory action to be considered when RAP re-convenes on 23 October.
		Monthly reports to monitor completion of DI training being run and a process for enforcement set up.
		Two serious adverse events and one serious adverse reaction reported for the human application sector. All are still undergoing investigation.
17. A review of the Licensing Management System is completed and changes, where necessary, agreed.		First draft of the Licensing Management System user manual complete.

D. Better organisation – flexible and efficient		
18. An effective corporate support strategy is in place.	Review service level agreements (SLAs) with Human Fertilisation and Embryology Authority (HFEA) (Q2)	
19. The organisation has a clear view of the actions that need to be taken in order to be flexible, efficient and effective.	Agree with DH the resource consequences of the organisational review and plan its implementation (Q1)	Business case submitted to DH. Awaiting feedback.
	Complete implementation of organisational review (Q2)	
	Authority approval of strategic plan (Q3)	
20. Work is prioritised across directorates to establish a clear view of roles, responsibilities and resources.	Business objectives converted to staff objectives and work plans (Q1)	
21. Clear organisational governance is in place and understood by all staff and stakeholders	Complete induction of new Authority members (Q1)	Completed. Senior management team and deputy chair of audit committee attended risk management training day.
	Hold quarterly accountability meeting with DH.	Held quarterly accountability meeting with DH. Progress against business plan for Q1 and strategic risks discussed.
	Complete review of current data protection (security) (Q1)	
22. A systematic review of staff development needs is completed	Revise corporate learning programme (Q2)	Consultant appointed to create learning and development framework.
23. Arrangements have been put in place to maintain a stable workforce	Implement a full complement of bespoke HR policies (Q1)	Issued to staff.
	HR strategy completed (Q3)	
24. The HTA has sufficient funds to achieve its broadened regulatory functions	Agree additional grant-in-aid (GIA) 2008/09 with DH (Q1)	DH agreed GIA cash element of £180k.
	Agree with DH GIA settlement for next three years (Q3)	Preparatory teleconference held with Head of Arms Length Body Business Support Unit and DH.
	Obtain Authority approval of revised fee structure (Q3)	
	Authority approval of strategic and business plans (including budget) (Q3 and Q4)	

25. We are prepared for our accommodation changes	Agree with DH the HTA's accommodation needs (Q2)	Accommodation case currently drafted. To be revised and submitted to DH when the likely outcome of the organisational review is known.
	Agree plan for move to new accommodation (in 2009–10) (Q4)	Not applicable until the above has been agreed.
26. An internal knowledge management system (policies and procedures platform) has been designed and implemented	Launch 'policies and procedures' platform (Q1)	Implementation of Sharepoint continues and is on schedule. The new system will be called the Information Management Platform and Communications Tool (IMPACT).
27. Enquiries are managed in a timely, appropriate and accurate way.	Implement recommendations of the enquiries audit (Q2)	Enquiries audit completed and Director of Communications considering recommendations.
		95 enquiries received. 99% answered within 20 days.