

## HTA Chief Executive's business plan and communications report 1 May – 30 May 2008

Business objective	Milestones	Progress over the month
<b>A. Better regulation and legislation – strategic, proportionate and rigorous</b>		
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 Working Group on implementation.
	Hold workshop with DH and other agencies on European Commission (EC) Donation Directive and implications for competent authorities (Q2)	Draft paper on functions of Competent Authorities sent to DH. Revised drafts of working papers for EC Action Plan and EC Donation Directive received from DH for review.
	Agree Authority statement on presumed consent (Q3)	HTA Chair continues to be a member of ODTF on presumed consent. SG and Helen Shaw are members of the ODTF communications sub-group. Chair gave presentation to ODTF on directed deceased donation.
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	Project initiated and planning commenced.
	Prepare for Hampton Implementation Review (Q4)	
		Attendance at UK Stem Cell Bank steering committee.
		Attendance at DH workshop on developments in cord blood collection.
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.		SM attendance at meeting of Competent Authorities in Brussels.
	Submit annual report of serious adverse events and reactions to the EC (Q2)	HTA invited to participate in pilot to report serious adverse events and reactions to the EC.
	Authority approval of strategic plan (Q3)	
	Prepare three year report of all activities at tissue establishments and associated inspection and control measures for submission to the EC (Q4)	EC provided further guidance on content of report and project to be initiated.
	Revised codes of practice complete passage through Parliament (Q4)	Code of practice revision programme on target.
	Develop a methodology to implement a system to license all human application (HA) procurement organisations from 5 July 2008	
		Workshop held with Authority members and external stakeholders to consider issues around directed deceased donation.

<b>B. Better communication and consultation – engaged stakeholders and an informed population</b>		
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	Sent letters to Wellcome Trust and Medical Research Council requesting meetings.
5. Major existing stakeholder relationships are reviewed	Complete survey of impact of the HT Act on the research community (Q3)	
		Proposal from York University on stakeholder evaluation reviewed. Kate Robson-Brown has also contacted York University about this potential project.
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)	Conference date and venue confirmed. The conference will be held at the Wellcome Collection Conference Centre on 5 November 2008. Minister invited to provide key note speech at the conference.
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)	Drafting of key messages guide has been completed. The guide will now be circulated to Authority members and external reviewers for their feedback.
	Publish Annual Review and Annual Report and Accounts (Q2)	The text for the Annual Review has been completed and is a paper at the Authority meeting. Photo shoots of the case studies for the Annual Review are under way.
	Hold annual report-back meeting (Q2)	
	Hold public Authority meeting (Q2)	
	Hold public Authority meeting (Q4)	
8. Consult effectively on codes of practice and a revised fee structure	Prepare final pre-consultation set of revised codes of practice (Q1)	Research code and generic introduction approved by Authority. First draft of glossary for codes completed.
	Complete series of consultation workshops on revised codes of practice (Q2)	
	Conclude consultation on codes of practice (Q3)	Consultation arrangements agreed by SMT. Paper on consultation arrangements is an item for discussion at the Authority meeting.
	Consult on fee strategy (Q3)	
9. Targeted sector-specific communications are developed	Complete website review incorporating sector-specific sections (Q2)	
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	
		Revised policy framework for relevant material – incorporating policies on the classification of blocks and slides as relevant material and guidance on the classification of other specific materials – drafted for review at Emerging Regulatory Policy Programme Board meeting.
12. A new regulation methodology for licence renewals is developed for implementation in 2010.		First draft project plans written for all sectors.
13. Sector-specific regulatory strategies are implemented.	Complete sector specific regulatory strategies (Q1)	First draft regulatory strategies for anatomy and research written. Regulatory strategies for post mortem (PM) and HA issued to Regulation Members Group (RMG).
	Fully implement Quality and Safety Regulations (Q2)	
	Complete review of fee strategy (Q2)	
	Complete Independent Assessor (IA) re-accreditation (Q4)	Revised reaccreditation processes and timeframes agreed by Transplant Working Group (TWG).
14. Facilitate compliance with legislation through a risk-based programme of inspections.	Prepare summary report of 2007/08 inspection findings (Q1)	Summary inspection reports for all sectors in progress. RMG approved essay plans and agreed project structure.
	Conduct 120 phase 2 inspections in Qs 1–4	16 phase 2 inspections completed: – One anatomy – Three PM – Three research – Nine HA – Three Regulatory Action Panels (RAPs) convened.  Suspension of phase 2 inspections for Q2, to focus on issuing licences to procurement organisations.  Project initiated for improving inspection scheduling.
	To complete all phase 1 inspections of new licence applications for procurement organisations (estimate 200) due to be received by 5 July 2008 (Q2)	Two HA licence applications under evaluation. Planning underway for staff training and workflow management during July – September.  12 organisations have contacted the HTA so far to indicate that they intend to apply for a procurement licence. Organisations have been asked to contact us by 13 June and apply for a licence by 5 July.
	To complete all phase 1 inspections of new licence applications for organisations applying for licences under the HT Act	Two research licence applications under evaluation.
		First draft of HA inspection manual complete and being user-tested by Regulation Managers.
15. Manage the live organ and bone marrow transplant approval programme (with increased numbers).		Transplant approvals: – One Accredited Assessor (AA) report received and one approved – 72 IA reports received and 71 approved – One adult-to-adult liver case referred to a panel
		TWG meeting held.

		Transplant Online Submission Systems are being moved from current hosting arrangements to allow further development.
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16. Non-compliance issues are rigorously addressed through a range of actions including, where necessary, enforcement.		Enforcement action carried out on one establishment storing material on unlicensed premises.  Three RAPs held.
17. A review of the LMS is completed and changes, where necessary, agreed.		Project initiated for a Licensing Management System (LMS) user manual.  Audit being undertaken of post inspection paperwork against the LMS and condition tracker.
		Review of HTA anatomy forms and Anatomy Online Submission System (AOSS) is under way.

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)	Discussion with HFEA continues. Legal SLA has been reviewed by SMT and further action is on hold pending the outcome of the organisational review. HR SLA has also been reviewed and changes are in place.
		Secure remote working capability has been established. Work to create secure data transfer with UK Transplant is under way.
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)	
	Complete implementation of organisational review (Q2)	
20. Work is prioritised across directorates to establish a clear view of roles, responsibilities and resources.	Business objectives converted to staff objectives and workplans (Q1)	Staff appraisals including objectives completed by 31 May.
		Individual training / development needs identified in performance appraisals.
		An audit of job descriptions is currently under way and will be completed by 30 June.
21. Clear organisational governance is in place and understood by all staff and stakeholders	Complete induction of new Authority members (Q1)	New member induction day planned for 12 June.
	Complete review of current data protection (security) (Q1)	Data protection project under way. Risks identified and main tasks to mitigate / remove risks are nearing completion. Data protection policy, record retention schedules and process for handling requests are complete. Training pack is under review and staff training to be held on 24 July.
		Compliance requirements with DH Information Governance Assurance Programme (IGAP) have been identified. Impact of requirements on HTA are being addressed.

22. A systematic review of staff development needs is completed	Revise corporate training programme (Q2)	Training courses held for staff on project management and presentation skills.
23. Arrangements have been put in place to maintain a stable workforce	Implement a full complement of bespoke HR policies (Q1)	HR policies have been ratified by employment lawyers and are currently being reviewed by the Chief Executive.
	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)	
	Agree with DH GIA settlement for next three years (Q3)	
	Obtain Authority approval of revised fee structure (Q3)	
	Authority approval of strategic and business plans (including budget) (Q4)	
25. We are prepared for our accommodation changes	Agree with DH the HTA's accommodation needs (Q2)	Draft business case produced. Review taking place week commencing 9 June before submission to DH.
	Agree plan for move to new accommodation (in 2009–10) (Q4)	
26. An internal knowledge management system (policies and procedures platform) has been designed and implemented	Launch 'policies and procedures' platform (Q1)	Tender responses received for the development of the policies and procedures platform.
		Employee leaver Standard Operating Procedure (SOP) drafted incorporating exit interviews and knowledge transfer. Generalised data from exit interviews will be given to SMT quarterly.
27. Enquiries are managed in a timely, appropriate and accurate way.	Implement recommendations of the enquiries audit (Q2)	
		232 enquiries received. 99% answered within 20 days.