Department of Health

Triennial Review of Human Tissue Authority

A Review of Human Tissue Authority (HTA)

Call for evidence

July 2015

Department of Health

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Triennial review of the Human Tissue Authority (HTA)

Introduction

In recent years, the health and social care system in England has undergone substantial change. The Health and Social Care Act 2012 and the Care Act 2014 have devolved functions and powers away from the Department of Health to local and Arm's Length Bodies.

The Department has the key stewardship and assurance function designed to ensure that the new system and multiple new and reformed bodies within it have the appropriate functions and are performing to a high standard.

To perform this stewardship function, the Department has put in place Triennial Reviews of all of its Arm's Length Bodies. This includes all Executive Non-Departmental Public Bodies (ENDPBs), Advisory Non-Departmental Public Bodies (ANDPBs), Executive Agencies and Special Health Authorities (SpHA). As an ENDPB the Human Tissue Authority (HTA) is subject to review in 2015-2016.

The programme of reviews uses the approach developed by the Cabinet Office as part of their work on Public Bodies Reform.

This is a Call for Evidence regarding the Human Tissue Authority (HTA). The focus of this Call for Evidence is on the HTA's responsibility for regulating the removal, storage and use of human tissue and organs as well as providing approval for organ and bone marrow donations from living people.

Purpose of the review

As noted above, this review is part of a wider programme the Department of Health has redeveloped as part of its stewardship and assurance function. The review will have two main stages:

- The first is to provide a robust challenge of the continuing need for the HTA – both in terms of the functions it performs, and the way in which these are delivered.

- If it is agreed that the HTA should retain its current function and utilise the same delivery model, the second stage of the review will then consider its performance, capability and governance, as well as considering opportunities for efficiencies.

This Call for Evidence will seek views from respondents on both of these stages.

Previous reviews of the HTA

The Department of Health published a report reviewing of all of its arm's length bodies in 2010. This report recommended that both the HTA and the Human Fertilisation and Embryology Authority (HFEA) should have their functions transferred to the Care Quality Commission and a new research regulator. However, the majority of responses to a consultation on this proposal in 2012 were opposed to such a move and this led to a further review by Justin McCracken in early 2013. This review considered a range of options, including merging the HTA and HFEA, but concluded that they should remain as separate Non-Departmental Public Bodies. This was agreed by the Department of Health and the Cabinet Office. The review also made a number of recommendations about the scope for efficiencies and improvements in the way that the HTA and HFEA undertook their functions.

This Triennial Review will take full account of these previous reviews and will not seek to reopen recent decisions. The Triennial Review will also include an assessment of the implementation of the recommendations in Mr. McCracken's review.

About the HTA

The HTA is an Executive Non-Departmental Public Body of the Department of Health and was 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.

In addition to the Authority's responsibilities for licensing under the HT Act, the HTA is the Competent Authority in the UK under two sets of European legislation, and is thereby responsible for ensuring the safety of human tissue and cells used for human application and organs used for transplantation.

In relation to organ donation, the HTA also regulates the donation of solid organs from living people to ensure that valid consent has been given and that no reward is sought or offered. This is done through an independent assessment process carried out by trained professionals at clinical centres throughout the UK. The Authority fulfils a similar role for living donation of bone marrow and peripheral blood stem cells from children without competence and adults who lack the capacity to consent.

The Human Transplantation (Wales) Act 2013 will come into force on the 1 December 2015 and will introduce, in Wales, provisions for consent to organ donation to be deemed in certain circumstances. The HTA will have a role in superintending the Act, and has produced a draft Code of Practice for professionals in Wales working in this area.

The overall strategic goal of the HTA is to maintain and further enhance public confidence in these activities by ensuring that they are undertaken safely and ethically, and with proper consent.

The HTA licenses 852 premises that store and use human tissue and organs for purposes such as research, human application, post-mortem examination, teaching, public exhibitions and organ transplantation. It publishes standards that licensed establishments must meet on consent; governance and quality systems; premises, facilities and equipment; and disposal. It also inspects and audits organisations to ensure that they maintain good standards of practice and follow appropriate procedures.

The HTA has a number of statutory functions. It may restrict or prevent the activities of an organisation which does not meet its standards. It also has a duty to inform members of the public, professionals and the Secretary of State for Health about issues within its remit. It does this by issuing Codes of Practice, which outline the standards and provide clear guidance for licenced establishments. In addition, information is provided on the HTA website, and helps members of the public make informed decisions.

Further details about the HTA are available at: https://www.hta.gov.uk/about-us

Useful links

Human Tissue Authority
https://www.hta.gov.uk/

Cabinet Office Triennial Review guidance
https://www.gov.uk/government/collections/triennial-review-reports

Human Tissue Authority Corporate Publications
https://www.hta.gov.uk/corporate-publications

Timeline

The Triennial review commenced on **25th June 2015** and is expected to conclude by the end of December 2015. The conclusions of the review will be announced in both Houses of Parliament and a copy of the final report will be published on the Department of Health website.

Responding to the call for evidence

In order to conduct the review in an open and transparent manner and ensure that the findings are rigorous and evidence-based, the review team is seeking views from a wide range of stakeholders. We are interested in the views of individuals and organisations that engage with the HTA or have a wider interest in its operations. These stakeholders include, but are not limited to, individuals, researchers, medical practitioners, transplantation organisations, civil society groups, and other health and care institutions.

The call for evidence will run from 14 July 2015 to 31 August 2015.
Responses can be provided by:

i. Completing the online questionnaire, which can be accessed at https://consultations.dh.gov.uk/triennial-reviews/human-tissue-authority-hta-call-for-evidence
ii. Emailing the review team at TR-HTA@dh.gsi.gov.uk.
iii. Attending a workshop (see below) where stakeholders can share their views directly with the review team.

Where options ii. or iii. are used, please also consider to what extent the response covers the key lines of enquiry that are set out in the online questionnaire and are replicated below, it would also be helpful to know the extent of engagement between respondents and the HTA, and the interests represented.

Workshops

Interested stakeholders are also invited to attend workshops to share their views on this Call for evidence:

Date:	**Time:**	**Location**
29 July 2015	10:00 – 12:00 hours	Richmond House, London
https://www.eventbrite.co.uk/e/human-tissue-authority-hta-workshop-tickets-17208512123		
12 August 2015	10:00 – 12:00 hours	Richmond House, London
https://www.eventbrite.co.uk/e/human-tissue-authority-hta-workshop-tickets-17208525162		
17 August 2015	10:00 – 12:00 hours	Quarry House, Leeds
https://www.eventbrite.co.uk/e/human-tissue-authority-hta-workshop-tickets-17585356274		

You can book a place through the links above. Places are limited and allocated on a first-come first-served basis

The Call for Evidence Questions

For all options, you do not have to answer all of the questions – please feel free to answer as many or as few as you like. Your evidence should consist of objective, factual information about the impact or effect of the HTA's approach to health and social care. Where possible, please give specific examples. Where your evidence is relevant to other review reports, we will pass your evidence over to the relevant report teams.

Only information directly relevant to the areas of investigation will be considered. Information where relevance is not demonstrable will not be taken as evidence. The review team is unable to respond to individual cases or consider complaints other than as part of the evidence for the review where it falls within the terms of reference.

Complaints should be directed to the HTA at enquiries@hta.gov.uk or the complaints officer telephone: 020 7269 1900.

Patient identifiable information should not submitted.

The review team is particularly interested in evidence in support of responses to the questions set out below but does not seek to restrict responses provided they are relevant to the key lines of enquiry. If you wish to send us supporting documentation please email as an attachment to TR-HTA@dh.gsi.gov.uk.

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances; this will mean that your personal data will not be disclosed to third parties.

Call for evidence

About you

Name:

Email:

Postal Address:

Organisation:

Would you categorise your response as from:

Individual

Public sector

Charitable/voluntary sector healthcare organisation

Clinical research

Medical/Academic schools

Private sector – Pharma

Private sector - Other

None of the above Please state:

……..

If your response is from an umbrella organisation representing a wider membership, please indicate the number of members consulted and the number of responses received: ……...

Please indicate what interactions/relationships you have with the HTA:

……

Questions

Form and Functions

The questions that follow are intended to frame the Triennial Review Call for Evidence. The questions presume an understanding of the functions, form and purpose of the HTA, some of which are listed below for information:

The HTA's principal functions are to:

- Inform the public, professionals and the Secretary of State for Health about issues within their remit by providing guidance for professionals, including codes of practice and information to the public to help them make informed decisions
- License organisations that store and use organs and tissue for purposes such as research, human application, post-mortem examination, teaching, organ transplantation and public exhibitions.
- Inspect organisations to check that they maintain high standards and follow appropriate procedures.
- Ensure the safety and quality of human tissue, organs and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive (**EUTCD**)
- Ensure the quality and safety of organs intended for transplantation, in compliance with the European Union Organ Donation Directive (**EUODD**),
- Regulate, through an independent assessment process, the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others.
- Regulate living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.
- Oversee the consent requirements of the Human Tissue Act for deceased organ donation.

Functions

1. Is there a continuing need for the functions undertaken by the HTA?

   ☐ Yes
   ☐ No
   ☐ Don't Know

   - Are there any functions you believe could be dropped or undertaken by another organisation?
   - Are there any functions that you think are needed but are not currently being undertaken?
   - Are there gaps or overlaps in the HTA's role which should be addressed?
   - Could the function be merged with those of another public body?

   Please briefly explain your answer

……..

2. How well do you think that the HTA fulfils each of its functions at present?

   ☐ Very well
   ☐ Well
   ☐ Average
   ☐ Poorly
   ☐ Very poorly
   ☐ Don't Know

   Please provide reasons for your answer

   ……..

Form

3. (a) Recent reviews have considered and rejected possible merger of the HTA with both the Human Fertilisation and Embryology Authority and a combination of the Care Quality Commission and the Health Research Authority.

   Outside of the options outlined above that have previously been considered which of the following organisational forms would you support?

   ☐ Remain as a Non-Departmental Public Body
   ☐ Merge with another public body
   ☐ Undertake the functions within the Department of Health
   ☐ Become a mutual/voluntary sector organisation
   ☐ Don't know

   Please provide reasons for your answer

   ……..

   (b) Are there parts of the HTA's work that could be better done elsewhere in the public, private or not for profit sectors?

   ☐ Yes
   ☐ No
   ☐ Don't Know

   Please provide reasons for your answer

   ……..

Performance and Efficiency

4. How would you rate the performance of the HTA?

   ☐ Very good
   ☐ Good
   ☐ Average
   ☐ Poor
   ☐ Very poor
   ☐ Don't Know

   - In what areas, if any, could the HTA improve its performance?
   - What key indicators should be used to effectively measure the HTA's performance?

   Please provide specific examples of areas that would benefit from improvement

   ……..

5. Do you think that the functions of the HTA, regulatory or otherwise, (as outlined in Annex B) impose burdens that are:

   ☐ Proportionate
   ☐ Disproportionate
   ☐ Don't Know

   - Are risks managed appropriately?
   - How does the HTA's approach compare to that of other regulators?
   - Are they proportionate in their focus and application?
   - Do they go too far or not far enough?

   Please provide reasons for your answer

   ……..

6. How effectively does the HTA operate within and support the rest of the health and care system?

   ☐ Very well
   ☐ Well
   ☐ Average
   ☐ Poorly
   ☐ Very poorly
   ☐ Don't Know

   Please provide reasons for your answer

   ……..

7. How well does the HTA communicate and engage with stakeholders?

   ☐ Very well
   ☐ Well
   ☐ Average
   ☐ Poorly
   ☐ Very poorly
   ☐ Don't Know

   - Are relationships with stakeholders (including regulators and professional bodies and other organisations in the health and care system) effective?
   - How effective is engagement with the public and wider stakeholders?
   - How well does the HTA influence nationally and internationally?

   Please provide reasons for your answer

   ……..

8. Could the HTA do more to support innovation and new approaches in the area of human tissue and organs?

   ☐ Yes
   ☐ No
   ☐ Don't Know

   Please provide reasons for your answer

   ……..

9. Are there any measures you believe the HTA could take to deliver further efficiencies (whether reduced costs or improved use of resources)?

   ☐ Yes
   ☐ No
   ☐ Don't Know

   Please provide reasons for your answer

   ……..

10. How effectively does the HTA maintain public confidence that human tissue is regulated appropriately?

    ☐ Very well
    ☐ Well
    ☐ Average
    ☐ Poorly
    ☐ Very poorly
    ☐ Don't Know

    Please provide reasons for your answer

    ……..

Resilience

11. Is the HTA sufficiently forward-looking and responsive to new challenges and opportunities?

    ☐ Yes
    ☐ No
    ☐ Don't Know

    - Does the HTA have the capability and capacity to carry out its functions and respond to future challenges?
    - Does the HTA have a robust and effective strategy for responding to the changing demands and technologies?
    - Do you believe that the HTA is well-placed to respond to future challenges?

    Please provide reasons for your answer

    ……..

Governance

12. Does the HTA follow best practices in its governance arrangements?

- ☐ Yes
- ☐ No
- ☐ Don't Know

- How effective are the Board and Senior Management Team?
- Are the skills and levels of experience of the Board appropriate?
- Is the HTA open and transparent where appropriate?
- Are effective financial management processes in place?
- Does the HTA recruit the best people through open and fair processes?

Please provide reasons for your answer

……..

Other Comments

Are there any other issues or evidence you think the review team should take into account?

Please submit your answer here:

……

Thank you for taking the time to respond to this Call for Evidence.

Please return completed forms by 31 August 2015

Email to: TR-HTA@dh.gsi.gov.uk

Or

Write to: HTA Triennial Reviews Team, Department of Health, Richmond House, 79 Whitehall, Room 220, London SW1A 2NS.

Annex A – HTA Functions

The HTA's principal functions are to:

- Inform the public, professionals and the Secretary of State for Health about issues within their remit by providing guidance for professionals, including codes of practice and information to the public to help them make informed decisions
- License organisations that store and use organs and tissue for purposes such as research, human application, post-mortem examination, teaching, organ transplantation and public exhibitions.
- Inspect organisations to check that they maintain high standards and follow appropriate procedures.
- Ensure the safety and quality of human tissue, organs and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive (EUTCD)
- Ensure the quality and safety of organs intended for transplantation, in compliance with the European Union Organ Donation Directive (EUODD),
- Regulate, through an independent assessment process, the donation from living people of solid organs, bone marrow and peripheral blood stem cells for transplantation into others.
- Regulate living donation, in compliance with Scottish legislation, on behalf of the Scottish Government.
- Oversee the consent requirements of the Human Tissue Act for deceased organ donation.

Annex B

Strategic Aim One

To protect the public's interests by delivering excellent regulation

High level objectives:

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 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 robust regulation of living donation

d) To monitor changes in our environment and act where these changes have implications for maintaining public confidence

Strategic Aim Two

To maintain strong relationships with stakeholders and the interested public to improve the quality of our work

High level objectives:

a) To maintain and build confidence and awareness in our work amongst professionals and the interested public

b) To work collaboratively with others to reduce regulatory burdens and increase the impact of our work

c) To engage with stakeholders on matters that are important to them and influence them in matters that are important to us

d) To develop means to ensure the views of the interested public inform our regulatory approach

Strategic Aim Three

To have a skilled and motivated team who are proud to work at the HTA and are committed to achieving our objectives

High level objectives:

a) To maintain the HTA's positive working environment and culture, and uphold the values of the organisation

b) To lead, motivate, involve and support colleagues to deliver excellent work

c) To attract and retain the right people with the right skills

d) To improve expertise and support delivery through high quality learning and development

Strategic Aim Four

To seek continuous improvement in the way we run the HTA and our value for money for licence holders and the public

High level objectives:

a) To maintain governance arrangements which give appropriate oversight to matters within the HTA's legislative remit

b) To maintain high quality management skills and practices

c) To maintain and improve cost-effectiveness and quality by systematically reviewing systems, processes and procedures, and by working with others

d) To ensure the continued financial viability of the HTA

*** END ***