HTA
Human Tissue Authority

Human Tissue Authority Fees Model Consultation Response

December 2016

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Background

1. The Human Tissue Authority (HTA) is an Executive Non-Departmental Public Body (ENDPB) sponsored by the Department of Health. We were established under the Human Tissue Act (HT Act) 2004 to regulate activities relating to the removal, storage, use and disposal of human tissue. The Act sets out the legal requirements for England, Wales and Northern Ireland. As a general rule, in Scotland this is done by the Human Tissue (Scotland) Act 2006. However, some provisions in the HT Act related to the analysis of DNA also cover Scotland.
2. The HTA is also the Competent Authority in the UK responsible for ensuring the safety of human tissue and cells used for patient treatment, in compliance with the European Union Tissue and Cells Directive (EUTCD). 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.
3. We license approximately 850 premises (including hub and satellite sites) across six sectors: Public Display, Organ Donation and Transplantation, Human Application, Post Mortem, Research and Anatomy.
4. The HTA's work on licensing and inspecting establishments, and the activities that support this, is required to be fully funded by the licence fees collected from each of the six sectors, in accordance with HM Treasury guidance. This accounts for around 73% of the HTA's total income (£3.3m in 2015/16), and pays for a wide variety of activities associated with our regulatory remit such as:
    a) assessing licence applications,
    b) making licensing decisions and issuing licences,
    c) site visit inspections and audits,
    d) providing advice and guidance to licensed establishments, and
    e) providing IT systems to support regulation.
5. We also regulate, through an independent assessment process, the donation of solid organs from living people. In addition, 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. This function is funded by Grant-in-Aid from the Department of Health.
6. The current fees structure was put in place in 2011, following a fundamental review in 2010 with involvement from our stakeholders. The current structure has served us well. However, there have been changes in the HTA's licensing and inspections process since then. Because of this, we reviewed the fees structure to ensure the impact of these changes is accounted for.

Consultation Overview

7. Following the review, a proposed fees structure was published in a document. The consultation was open from Monday 25 July – Friday 30 September 2016.

8. The consultation was supported with five webinars, two general and three sector-specific. These were promoted both on the HTA website and via communications to Designated Individuals, such as via the HTA stakeholder newsletter.

9. We sought feedback on the proposed changes to the fees structure, asking nine specific questions and inviting general comments. We received 29 responses to the consultation questions, representing all sectors with the exception of public display.

10. The response rate was relatively low. We believe this may be because the proposed 2017/18 fee levels were not significantly different for the majority of establishments.

11. Responses were largely positive or neutral. There were some individual responses that disagreed with parts of the proposed model. However, there were no significant issues raised which would require alterations to the proposed fees model. Consultation responses and HTA replies are included in paragraphs 18-35 of this document.

12. Following the consultation, responses were analysed and results presented to the HTA Stakeholder Group, Senior Management Team and Authority. Discussions also took place with the stakeholder who was most significantly affected by the proposals.

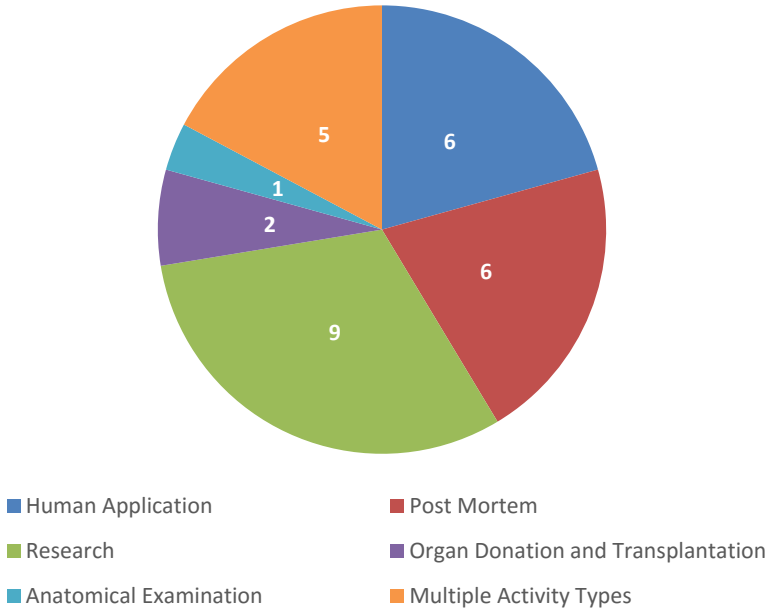
13. The revised model has now been approved by the Authority, and will be used to calculate fees for the 2017/18 cycle.

14. Thank you to those who engaged in the fee review and consultation process. We are grateful for your valuable input.

Consultation Responses

Sectors Represented

15. Responses were received from the following number of organisations per sector:



Responses to Consultation Questions

16. Respondents were invited to answer an online questionnaire. This included a series of general questions, followed by the option to answer sector specific questions.

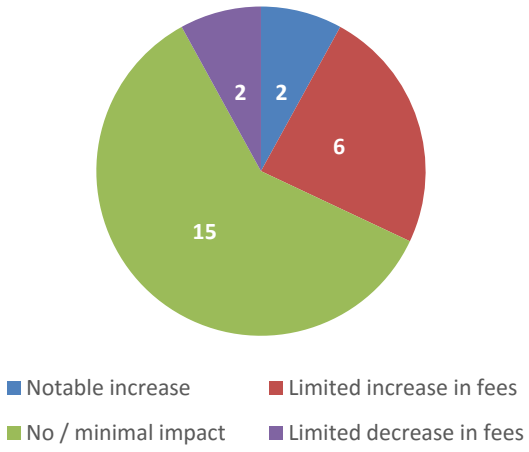
17. Please note that no responses were mandatory, and not all respondents answered every question relevant to their sector.

General Questions

18. Overall, the responses to the general questions were positive. The responses are summarised in the table below:

Question	Yes	No
Do you think the proposed changes are clear and easy to follow?	26	2
Do you agree that the proposed changes strike the right balance between a fees structure that is simple and transparent and one that reflects individual features of regulating sectors and establishments?	28	0
Do you agree that the proposed changes reflect and balance the principles the HTA applies to the fees review?	27	1
Do you agree that the proposed new satellite bands (with the same fee for each of the first four satellites and a smaller fee for the fifth and subsequent satellites) are appropriate?	21	2

19. To give context to the responses, we also asked establishments about the impact the proposed changes have for their establishment. For the majority of respondents, there would be no or minimal impact.



20. Following the general questions, we asked one question relating to the specific changes proposed for each of the following sectors:

    a) Public Display

    b) Organ Donation and Transplantation

    c) Human Application

    d) Post Mortem

21. These are the sectors where we proposed making significant changes to the fees structure. The responses to the sector specific questions are summarised below.

22. For the remaining sectors, we proposed keeping the fees model similar to the current model. Respondents from these sectors could provide feedback in the comments section at the end.

Public Display

23. Establishments in this sector were asked if they agreed with the proposal that it is more appropriate to charge all establishments in this sector the same main site fee.

    - *All respondents who answered this section agreed with this proposal. However, as noted previously, no Public Display establishments responded to the consultation.*

Organ Donation and Transplantation

24. Establishments in this sector were asked if they considered it fair and transparent to charge a fee that reflects the number of different types of organs each establishment is licensed for.

    - *All respondents agreed with this proposal.*

Human Application

25. Establishments in this sector were asked if they agreed with the proposal to charge establishments which have five or more different types of tissue more than those who have one to four tissue types.

    - *Eleven out of twelve establishments agreed with this proposal.*

Post Mortem

26. Establishments in this sector were asked if they agreed with the proposal to charge a base license fee then specific fees per activity undertaken. The activity types are:

    a) Carrying out a post mortem examination,

    b) storage for a scheduled purpose; and

    c) removal for a scheduled purpose.

    - *All respondents agreed with this proposal.*

Additional Comments Received

27. We received a number of positive comments, including multiple establishments noting that the proposed fee structure was ‘clear, simple and transparent’. One organisation stated that:

> *the move towards more structured fees is a logical approach allowing users to tailor their licences to their needs*

28. The following paragraphs summarise the additional comments we received.

Risk-based Model

29. Representatives from the Human Application and Post Mortem sectors questioned why we were not implementing a more risk-based model, including reducing fees for good compliance.

    - **HTA response**
      Introducing a more complex, establishment-based risk matrix to the fees model would be very resource intensive and would rely heavily on subjective assessment. We have therefore concluded that in the interests of transparency and ease of implementation, risk is best reflected by the regulatory activities undertaken to mitigate the risks posed in each sector. After thorough consideration, we also concluded that we should not charge for non-compliance. This would be inconsistent with the supportive ethos of the HTA, and could discourage open reporting of issues. The importance of the HTA being seen as supportive rather than punitive was noted in consultation feedback from another organisation.

Satellite Sites

30. There were two responses which disagreed with the change in banding for satellite site fees.

    - **HTA response**
      The proposed change is due to the regulatory effort required: when there are between one and four satellite sites, each site is inspected; when there are five or more, a sampling approach is taken. Because of this, we believe that there should be equal fees for each of the first four satellites. We have taken into consideration the comments received but feel that the change in fee levels for satellite sites is fair, so have kept changes proposed in the consultation document

Tissue Types

31. We were asked about the additional charge for establishments working with five tissues types or more in the Human Application sector.

    - **HTA response**
      This is again due to the amount of regulatory effort required during inspections and so have kept changes proposed in the consultation document.

Dormant Licences

32. An organisation in the Human Application sector suggested reducing charges for licences which are not being used.

- **HTA response**

  This is not being taken forward by the HTA. Regulatory effort is not significantly different when activities are not being undertaken. In addition, the administrative cost of implementing a system to do this would not be proportionate to the benefits seen. It should be noted, however, that licences can be revoked by establishments if they are unused and a new application submitted when required.

Payment in Instalments

33. One response noted that payment of fees in instalments would be beneficial, particularly for smaller organisations.

    - **HTA response**
      The HTA can arrange for fees to be paid in instalments; this is done on request rather than automatically.

Organ Donation and Transplantation

34. In this sector, one organisation was listed separately as it is expected to be affected significantly by the changes. This organisation queried the assumptions we made about time and regulatory effort dedicated to them. The organisation also provided information about planned efficiencies and a reduction in the number of licenced premises requiring inspection.

    - **HTA response**
      The HTA bases fee assumptions on evidence. This means potential future efficiencies cannot be taken into account until it is clear that they will impact on regulatory effort required. The HTA is committed to reviewing its assumptions regarding regulatory resource on an annual basis as part of the fee setting process. Any efficiencies that have been made by establishments that have a positive impact on the consumption of HTA regulatory resource will of course be reflected in the fees set in future.

35. These points were discussed with the organisation concerned, and agreement reached. Positive feedback was given around the HTA's engagement with this process.

Conclusions

36. After considering the consultation responses, we have decided that changes to the proposed fees model are not required. This has been agreed by the Human Tissue Authority's Senior Management Team and Board (The Authority).

37. As part of the consultation, we indicated that a budget increase was likely to be necessary. We provided indicative fee levels if the budget increase was the maximum amount we proposed of £250,000. We have kept the increase to the minimum needed, and fees are within the indicative ranges noted in the consultation document.

38. The Authority has approved a budget increase of £160,000 for the 2017/18 financial year. This means £3.4m must be recovered from fees.

39. The budget increase will fund two additional Regulation Managers and provide additional IT resource. This will enable the HTA to maintain and build on the quality of our regulation while also implementing key development work. This includes:

    a) enhancing our horizon scanning function to allow swifter, more proactive responses to emerging issues and innovations,

    b) implementing the outcomes from the Licensing and Inspection Review, such as increasing transparency on our approach to regulatory risk, and

    c) building stronger relationships with Designated Individuals through activities such as more frequent sharing of best practice.

40. Additional IT resource will enable prompt development of the improved portal which establishments use to review and submit information. This will help to streamline processes for both licenced establishments and for the HTA.

41. The approved fees for 2017/18 have been published alongside this consultation response on our website here.

Appendix 1: Summary of Changes per Sector

All Sectors:

- Setting different initial application fees for licences, depending on the sector, to better reflect the time spent by regulation staff on assessing licence applications in each sector including performing Licence Application Assessment Visits (LAAVs).
- Changing the banding for satellites to two groups (1-4 satellites and 5 or more satellites) to better reflect regulatory activity. If there are five or more satellites, the HTA adopts a sampling approach rather than considering every satellite.

Public Display:

- Charging the same fee to all establishments to reflect the similar levels of regulatory activity undertaken at each establishment across the sector regardless of the number of items held.

Organ Donation and Transplantation:

- Charging different fees based on the number of different organ types to better reflect that regulatory activity, in particular inspection site visit activity, varies depending on the number of different organ types an establishment transplants.

Human Application:

- Introducing an additional fee for establishments that have five or more different types of tissue as there is more regulatory activity, in particular inspection site visit activity, where establishments have five or more different tissue types compared to establishments with fewer tissue types.

Post Mortem:

- Charging fees within the Post Mortem sector depending on the activities undertaken:
    - post mortem examination;
    - storage of the body of a deceased person or tissue from a deceased person for use for a scheduled purpose; and
    - removal of tissue from the body of a deceased person, other than during a post mortem examination, for use for a scheduled purpose.

  The three activities generate different levels of regulatory activity, in particular inspection site visit activity.

Research:

- No changes are proposed to the annual fee structure for main licences in the Research sector as regulatory activity is similar for each establishment in the sector and is therefore still best represented by charging all establishments the same annual fee.

Anatomy:

- No changes are proposed to the annual fee structure for main licences in the Anatomy sector as regulatory activity is similar for each establishment in the sector and is therefore still best represented by charging all establishments the same annual fee.

Appendix 2: Approved Fees for 2017/18

Sectors (type of licence)	Post Mortem (PM)	Research	Public Display	Anatomy sector	Human Application (HA)	Organ Donation and Transplantation (ODT)	Removal Only
Main Licence fee:	£2,850	£3,100	£1,050	£2,250	£4,900	£3,450	£780
PM activities:							
● Making of a PM	£1,950	-	-	-	-	-	-
● Storage	£250	-	-	-	-	-	-
● Removal	£250	-	-	-	-	-	-
HA activities:							
● 5 or more tissue types	-	-	-	-	£850	-	-
● Processing	-	-	-	-	£2,450	-	-
● Procurement	-	-	-	-	£850	-	-
● Testing	-	-	-	-	£850	-	-
● Storage	-	-	-	-	£850	-	-
● Distribution	-	-	-	-	£425	-	-
● Import	-	-	-	-	£425	-	-
● Export	-	-	-	-	£425	-	-
ODT - two or fewer organs	-	-	-	-	-	£2,200	-
ODT - three organs	-	-	-	-	-	£4,400	-
ODT - four organs	-	-	-	-	-	£5,700	-
ODT - five or more organs	-	-	-	-	-	£7,300	-
Commissioning organisation for procuring organs from deceased donors	-	-	-	-	-	£25,000	-
Satellite licence fees: (First 4 satellites)	£1,850	£775	£200	£350	£2,850	-	-
Satellite licence fees: (Each satellite over 4)	£925	£375	£100	£175	£1,425	-	-
Application fees:							
Main licence	£2,500	£2,500	£2,500	£2,500	£4,000	£2,500	£320
Satellite	£550	£550	£550	£550	£800	-	-