



## **Guidance to completing the 2011 Tissues and Cells for Patient Treatment (Human Application) annual activity report**

It is important that you read this document before completing the online form. Inaccurate submissions may affect your licence fee.

## Key Points

- **Gather all your information first**; we are sorry that you will not be able to save and return to the submission.
- **Allow ten minutes** to complete the data submission for each tissue type.
- The deadline for completion is close of business **31 January 2012**.
- The online submission form can be found through this [link](#) or by pasting this URL into your internet browser software:

[http://forms.hta.gov.uk/\\_layouts/FormServer.aspx?XsnLocation=http://forms.hta.gov.uk/AA/Forms/template.xsn&OpenIn=browser&SaveLocation=http://forms.hta.gov.uk/AA](http://forms.hta.gov.uk/_layouts/FormServer.aspx?XsnLocation=http://forms.hta.gov.uk/AA/Forms/template.xsn&OpenIn=browser&SaveLocation=http://forms.hta.gov.uk/AA)

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## Overview

1. All Tissue Establishments (TEs) licensed during 2011 for **patient treatment** under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (the Regulations) must submit information on their activities during that year. This is a requirement of European Directive 2004/23/EC, article 10 (1).
2. The HTA submits a digested and anonymous set of data to EURO CET, who make this information available on their website in the form of bulk data for each country. The information is also submitted on request to the European Commission and additionally provides important background information for data analysis of serious adverse event and reaction reported in this sector.
3. Data submission must be via the online form that is open from 3 January 2012 and closes on 31 January 2012, on the HTA website. The online form can be accessed by following this link:

[CLICK TO OPEN THE ANNUAL ACTIVITY FORM](#)

4. We advise that you first read through all of this guidance and prepare the relevant information for submission before starting to complete the online form. Definitions of the activities about which we require information are given on page 11–13. It is important that you enter the correct data; once you have submitted your TE's annual activity report, you will no longer be able to make changes.
5. The online submission form must be completed in a single session using a web browser. You will not be able to save a partial submission, close the session, and then return to it later. We strongly advise you to collate all your information prior to completing the online submission forms.
6. You should provide data about activities undertaken between 1 January 2011 and 31 December 2011 at your licensed human application TE. You should also include licensable activities undertaken on your behalf at unlicensed third parties.

7. The information you provide in the annual activity return will be used to calculate your licence fees for the next year (2012/13). If any of your licensable activities change at any time email [licensing.enquiries@hta.gov.uk](mailto:licensing.enquiries@hta.gov.uk) with the information.
8. If you have any queries that are not addressed here, please contact the HTA on 020 7269 1900 or email [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk).

## Getting started

9. Firstly, collate your annual activity data. You will be asked questions relating to the types of tissues you have in your TE, and how many units were procured or received, processed, stored, sent to somewhere else, used or disposed. Think of units in terms of whole pieces of tissue or a sample of cells. For example, if a donation of peripheral blood stem cells results in five bags of preserved cells in storage, then this is a procurement of five units. We will also want to know how many donors were tested.
10. Secondly, check your current licence and the number of satellite licences, as you will be asked to confirm your licensed activities. Licensed activities related to tissues and cells are:
  - Procurement
  - Donor testing
  - Processing
  - Storage
  - Distribution
  - Import
  - Export
11. When you have collated your information and you are ready to submit the data, you need to access the online form. Set aside about ten minutes to complete the submission for each tissue type that you are submitting data on.
12. To access the online form follow this link:

[CLICK TO OPEN THE ANNUAL ACTIVITY FORM](#)

## Step-by-step guide

### General

13. There are three separate forms for you to use. The first is designed for you to give details of your establishment and your activities. In the second you will submit your activity data. In the third you may provide further information, will be asked for some feedback, and will make a declaration certifying that the information is correct when you click the 'submit' button.
14. At the end of each form are navigation buttons that allow you to move between forms. For example, you may need to add more tissue types by returning to the first form. You can move freely between the forms without losing previously entered data but if you close your browser before submitting your data you will need to start again.
15. If you wish to keep a record of what you have submitted, we recommend that you print each form using your web-browser software before you submit the information. You will not be provided with a copy of your data after submission.
16. Click 'submit' only when you have entered and checked all data. This button will submit the information to the HTA. You must click this button to submit the data to the HTA. **You will not be able to change your submission once you have clicked the 'submit' button.**

## Form 1 – Your details and activities



### Annual Activity Data submission for the Human Application Sector

#### Form 1 - Your Details and Activities

Unfortunately, you will not be able to save and return to this submission.  
Please ensure you have all the information you require before completing the forms.  
Refer to the guidance notes for more information.

Your details	
Name of the licensed establishment	<input type="text"/> *
Your five-digit licence number	<input type="text"/> *
Name of the person completing this submission	<input type="text"/> *
Your email address	<input type="text"/> *
Your daytime telephone number	<input type="text"/> *
Are you the designated individual or their representative?	<input checked="" type="radio"/> Designated Individual <input type="radio"/> Representative
Who should we contact regarding payment of licensing fees to the HTA?	Contact name: <input type="text"/> * Contact email (if known): <input type="text"/>
What is the address of your finance department?	Address: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Licensable Activities (please tick)
Procurement <input type="checkbox"/>
Donor Testing <input type="checkbox"/>
Processing <input type="checkbox"/>
Storage <input type="checkbox"/>
Distribution <input type="checkbox"/>
Import <input type="checkbox"/>
Export <input type="checkbox"/>

17. You will be asked to supply your contact details, and the identity of the licensed establishment for which you are submitting data. We will be asking you to provide contact details for the person to whom we should address invoices.

18. Using the tick boxes you will certify your licensed activities and record the number of satellite licences associated with the main licence. **Please note that we will use this information to calculate your licence fee for 2012/13.**
19. **Please see the 'Definitions' part of this document for more information about the different licensable activities.** Please email [licensing.enquiries@hta.co.uk](mailto:licensing.enquiries@hta.co.uk) to inform the HTA if the activities you have ticked for 2011 are expected to change in 2012. The information you provide to us will be used to determine the licence fee your establishment is charged in the next business year. Please ensure you familiarize yourself with these definitions, wrong information could result in your establishment being charged the wrong fee in 2012/13.
20. You will be asked to verify the types of tissues and cells you have worked with between 1 January and 31 December 2011, either at your TE or under the authority of your licence by an unlicensed Third Party. If the list does not include the tissues and cells you have worked with there is an 'other' option, where you can provide further details in the next view.
21. Finally, you will be asked if tissues or cells have been used as starting materials for Advanced Therapy Medicinal Products (ATMPs; e.g. for Autologous Chondrocyte Implantation) or Investigational Medicinal Products (IMPs; e.g. manufactured under GMP for use in a clinical trial).

## Form 2 – Data entry

### Form 2 - Data Entry

Using the information gathered in your tissue register for the period of 1 January to 31 December 2011, enter the number of units of each tissue type associated with each activity.

Bone	
Bone input to your establishment - record the number of units:	
imported from outside the EEA	<input type="text"/>
distributed to you from another establishment from within the UK or EEA	<input type="text"/>
procured under your licence from a donor	<input type="text"/>
Bone output from your establishment - record the number of units:	
used in a transplant/engraftment within your establishment	<input type="text"/>
distributed to another establishment within the UK or EEA	<input type="text"/>
exported to outside the EEA	<input type="text"/>
disposed of	<input type="text"/>
Bone storage within your establishment	
Please enter the number of units stored already on 1 Jan 2011	<input type="text"/>
We calculate your net change of units in 2011 as 0	
Therefore your stock at close of business 31 Dec 2011 was 0	
Activities associated with bone	
How many donors were tested under the authority of your licence?	<input type="text"/>
How many units were processed within your establishment?	<input type="text"/>
How much of your input was put into storage before use, distribution or disposal?	<input type="text"/>

If you wish to change your licensed activities or add more tissue types press this back button.

22. The length of this form will depend on the number of tissue types you have worked with. For each tissue type you will be asked to record data relating to tissue **input**, **output**, **storage** and other **associated activities**. You will only be able to record data for activities for which you hold a licence.

23. **Input:** Record here the number of units:

- a. imported from outside the European Economic Area (EEA)
- b. distributed to you from another establishment from within the UK or the EEA
- c. procured from a donor under the authority of your licence.

24. **Output:** Record here the number of units:

- a. used in a transplant/engraftment within your establishment
- b. distributed to another establishment within the UK or EEA
- c. exported to outside the EEA
- d. disposed of
- e. used as starting material for an IMP or ATMP within your establishment.

25. **Storage:** We would like to collect the number of units of each tissue / cell type you had in your possession at the beginning of the year, then, with the input and output data you have entered, calculate your current stock. You will be asked to record here the number of units that were stored at your establishment on 1 January 2011. The form will automatically calculate your stock at the close of business on 31 December 2011. **Please check that this calculation is correct.**

*For example, an establishment procured 10 heart valves during 2011, and distributed 12. It was able to do this because it started the year with a stock of five heart valves. The end of year stock was automatically calculated by the form to be three heart valves; the DI checked the freezer and found this to be correct.*

26. **Associated activities:** Record here how many donors were tested, and the number of units processed. There is an extra question regarding storage in this section specifically about the amount of input to your establishment that was put into storage at any time for more than 48 hours prior to use, distribution/export or disposal. Exclude units of tissue / cells if they were not stored for more than 48 hours.

*For example, an establishment licensed to store femoral heads received 50 units of bone in 2011, but used 20 of them without storing them for more than 48 hours. The answer to the question 'How much of your input was put into storage before use, distribution or disposal?' is '30'.*

27. EURO CET asks the HTA to collect additional information about the use of Haematopoietic Stem Cells. If you have worked with Peripheral Blood Stem Cells, Bone Marrow, Donor Lymphocyte Infusions, or Cord Blood we will ask you to record how many procurements were for autologous use, for allogeneic use through a registry, or for allogeneic use directed to an individual patient or a relative.
28. This form has built in data validation. For example, an error message will occur if you have a stock of stored tissues, but you have not indicated that you are licensed to store tissue. Or, you will not be able to record more units put into storage than you have received or procured. **You will not be able to submit your data if there are errors on this form.** If a data validation error message occurs, but you are sure that you have entered the correct information, you must speak to someone at the HTA (020 7269 1900) to resolve the problem.

### **Form 3 – Further information, feedback and submission**

29. This form has a free-text space to provide further information relevant to your annual activity data. For example, if you have had errors on the form and had to resolve them with the HTA's advice you must use this space to explain why you think these data are accurate. Please also use this space if the stock calculation differs from your stock check.
30. There is a non-obligatory feedback section, asking questions relating to the annual activity data submission process.
31. Before you submit these data, you will be asked to agree to a declaration statement, confirming that the information provided is accurate.

Once you have submitted the information you will receive an email confirming submission.

## Definitions

### Activities

32. As part of your submission you will need to provide information about the level of your licensable activities as well as additional activities that may be carried out at your TE (e.g. release for treatment and disposal). We require the latter information for our submission to EURO CET.

33. **Procurement** – Establishments involved in retrieving tissues or cells from donors within the UK, carried out by your own establishment or an unlicensed third party on your behalf. Procurement includes autologous donations as well as allogeneic donation. However, tissues and cells used as an autologous graft within the same surgical procedure (removed and transplanted back to the same individual without being subjected to any banking process or processing outside theatre), are excluded from the Tissue and Cells Regulations, and are not reportable.

34. *Procurement as a licensable activity is not:*

- a. Buying tissues and cells released for end use (e.g. from other licensed establishments in the UK such as NHS Blood and Transplant).
- b. Receipt of tissues and cells for processing where these have been procured by another licensed establishment.
- c. Obtaining the material outside of the UK and shipping it into the UK; such an activity is classed either as distribution in (where material is obtained from another accredited establishment within the EEA) or as import.

35. **Donor Testing** refers to donor blood testing that has been performed to establish the serological status of the donor (including autologous donors) carried out by your own TE or an unlicensed third party on your behalf.

36. **Processing** carried out by your own TE or an unlicensed third party on your behalf, includes all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human applications. All processed units should be included in this number, even if they are not released or distributed. The units for processing should be considered to be equivalent to those of the final product. Processing is not the processing of test results.
37. **Storage** – Storing tissues or cells intended for human application *for more than 48 hours* at the licensed TE. Any storage for periods less than this time is not licensable. Reportable are units that have been *put into storage* in 2011; a separate calculation is made regarding your stock at the beginning and the end of the year. You will not be able to report storage of more units than you have received or procured. Storage must be carried out by a licensed establishment and cannot be subject to a third party agreement with an unlicensed third party.
38. **Distribution** – carried out by your own establishment or an unlicensed third party on your behalf. This activity takes place whenever tissues or cells are moved between establishments in the UK or to another licensed establishment in the EEA. See paragraph 140-142 of the [Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment](#) for a full definition. You will be asked to submit information regarding the number of units of tissue you have distributed to another TE within the UK or EEA for either end use or for other activities (e.g. processing or storage).
39. **Import** – applies only to countries outside the European Economic Area (EEA). The EEA consists of the 27 Member States of the European Union in addition to Iceland, Norway and Liechtenstein. Tissue procured outside the EEA, also on behalf of the TE (as in the case of cord blood) should be reported as ‘imported’ not ‘procured’.
40. **Export** - Tissues and cells exported from the UK to countries outside the EEA.

## General

41. **Tissue Establishment (TE)** – a tissue bank or a unit of a hospital or another body where activities of donation, procurement, testing, processing, preservation, storage, distribution, import or export of human tissues and cells for human application are undertaken. The establishment will be licensed under The Human Tissue (Quality and Safety for Human Application) Regulations 2007.
42. **Starting material for an ATMP or IMP** – Advanced Therapy Medicinal Products (ATMPs) or Investigational Medicinal Products (IMPs) may originate from tissues or cells. For example, please record tissues that have been dissociated into cell lines with the intention of expanding them to ATMPs or IMPs. Please also record tissues that have been taken from your TE to be used as starting materials for an ATMP or IMP by a manufacturer; this is the case for knee chondral tissue used to make an ATMP for Autologous Chondrocyte Implantation. The procurement and testing of tissues and cells for use as a starting material in ATMPs or IMPs falls under the remit of the HTA. For a definition of the different types of ATMPs please refer to the ATMP Regulation 1394/2007/EC.
43. **Distributed to you** – applies to units of tissue or cells that have not been donated and procured under the authority of your licence, but have been received by your TE from another TE within either the UK or the EEA.

## Units for different types of tissues and cells

- **Skeletal tissues** – One unit is one individually packaged graft (e.g. one femoral head, one unit of demineralised bone, one container of bone chips, one femoral strut, one individually packaged tendon or part of a tendon).
- **Haematopoietic Stem Cells** – One unit is one single bag or container of cells
- **Ocular tissues** – One unit is one individually packaged or contained graft (e.g. one cornea, one piece of sclera).
- **Cardiovascular tissue** – One unit is one individually packaged graft (e.g. one valve, one package containing one or more lengths of vessel).

- **Whole skin** – One unit is one container of tissue regardless of the area of skin it contains.
- **Amniotic membrane** - One unit is one container of tissue, regardless of the area of tissue it contains
- **Expanded cells** – You will be asked to record the number of vials (or other type of container) that have been stored as well as the number of cells per vial.
- **Adipose tissue (e.g. adipocytes)** – One unit is one individually packaged container of tissues or cells.

**For further assistance in defining units of tissues or cells please call the HTA on 020 7269 1900, or email [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)**