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**Date** 16 June 2014

[REDACTED]  
[REDACTED]  
[REDACTED]  
By email to [REDACTED]

Dear [REDACTED]

### **Freedom of Information request**

Thank you for your request for information dated 10 June 2014, which we received as follows:

“I would like to make the following request under the provisions of the Freedom of Information Act 2000.

1. How many reports of serious adverse events and /or reaction that are linked to the procurement of human tissues and cells for human application have been received in the last three years? Could the information please be provided on a year by year basis, with the most up to date information available (ie 2014, 2013, 2012).

If this is not possible then the most up to date information available please.

2. How many reports of serious adverse events and /or reaction that are linked to the testing of human tissues and cells for human application have been received in the last three years? Could the information please be provided on a year by year basis, with the most up to date information available (ie 2014, 2013, 2012).
3. How many reports of serious adverse events and /or reaction that are linked to the processing of human tissues and cells for human application have been received in the last three years? Could the information please be provided on a year by year basis, with the most up to date information available (ie 2014, 2013, 2012).
4. How many reports of serious adverse events and /or reaction that are linked to the distribution of human tissues and cells for human application have been received in the last three years? Could the information please be provided on a year by year basis, with the most up to date information available (ie 2014, 2013, 2012).

5. How many reports of serious adverse events and /or reaction that are linked to the storage of human tissues and cells for human application have been received in the last three years? Could the information please be provided on a year by year basis, with the most up to date information available (ie 2014, 2013, 2012).”

## Response

We can confirm we have treated your email as a request under the Freedom of Information Act (FOIA).

Serious adverse events (SAEs) are reported against the licensable activity they are linked to, such as 'storage' in the case of freezer failure. Serious adverse reactions (SARs) are reported as donor or recipient reactions, depending on whom the reaction has occurred in.

The information you have requested is available on the HTA's website up until 31 December 2013, in accordance with our Publication Scheme. The data forms part of our quarterly Regulatory Activity Reports (RARs) which are discussed at Authority meetings. I have provided the webpage links to this information for your reference:

- Data for quarter 2 of 2012/13 until quarter 3 of 2013/14 is on page 16 of the RAR in this paper:  
[http://www.hta.gov.uk/db/documents/Papers\\_for\\_the\\_March\\_2014\\_HTA\\_Authority\\_meeting.pdf](http://www.hta.gov.uk/db/documents/Papers_for_the_March_2014_HTA_Authority_meeting.pdf)
- Data for quarter 1 of 2012/13 is on page 9 of the RAR in this paper:  
[http://www.hta.gov.uk/db/documents/September\\_Authority\\_papers\\_2.pdf](http://www.hta.gov.uk/db/documents/September_Authority_papers_2.pdf)
- Data for quarter 4 of 2011/12 is on page 9 of the RAR in this paper:  
[http://www.hta.gov.uk/db/documents/Papers\\_for\\_the\\_May\\_Authority\\_meeting.pdf](http://www.hta.gov.uk/db/documents/Papers_for_the_May_Authority_meeting.pdf)
- Data for quarter 3 of 2011/12 is on page 10 of the RAR in this paper:  
[http://www.hta.gov.uk/db/documents/Authority\\_paper\\_January\\_2012.pdf](http://www.hta.gov.uk/db/documents/Authority_paper_January_2012.pdf)
- Data for quarter 2 of 2011/12 is on page 9 of the RAR in this paper:  
[http://www.hta.gov.uk/db/documents/Authority\\_papers\\_November\\_2011.pdf](http://www.hta.gov.uk/db/documents/Authority_papers_November_2011.pdf)
- Data for quarter 1 of 11/12 is on page 8 of the RAR in this paper:  
[http://www.hta.gov.uk/db/documents/Papers\\_for\\_the\\_July\\_public\\_Authority\\_Meeting.pdf](http://www.hta.gov.uk/db/documents/Papers_for_the_July_public_Authority_Meeting.pdf)

The information you have requested from 1 January 2014 until 10 June 2014 has not yet been published on the HTA website.

Data for quarter 4 of 2013/14 can be found in the table below:

<b>Process or patient incident linked to</b>	<b>13/14 Q4</b>
Procurement	2
Processing	0
Testing	1
Storage	2
Distribution	2
End use	0
Transportation	1
Preservation	1
Materials	1
Other	7
Donor reaction	0
Recipient reaction	11
<b>Total number of SAEARs during Q4 2013/14</b>	<b>28</b>

Data for SAEARs which were reported to the HTA from 1 April 2014 to 10 June 2014 can be found in the table below:

<b>Process or patient incident linked to</b>	<b>13/14 Q4</b>
Procurement	2
Processing	2
Testing	2
Storage	2
Distribution	1
End use	0
Transportation	0
Preservation	0
Materials	1
Other	3
Donor reaction	1
Recipient reaction	3
<b>Total number of SAEARs from 1 April – 10 June 2014</b>	<b>17</b>

This data will be published in the Authority papers section of our website within the next eight weeks: <http://www.hta.gov.uk/aboutus/authoritymeetings/authoritymeetingspapers.cfm>.

## Further information

If you are unhappy with the way the HTA has handled your request for information in this case, you may in the first instance ask us for an internal review by writing to us at the above postal or email address.

If you remain dissatisfied with the handling of your request or complaint, you have the right to appeal directly to the Information Commissioner for a decision, at the address below:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire SK9 5AF

Telephone: 08456 30 60 60  
or 01625 54 57 45

Website: [www.ico.gov.uk](http://www.ico.gov.uk)

There is no charge for making an appeal.

Yours sincerely

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