

Human Tissue Authority
151 Buckingham Palace Road
London
SW1W 9SZ

██████████

By email to ██████████

Tel 020 7269 1900
Web www.hta.gov.uk
Email enquiries@hta.gov.uk
Date 2 May 2019

Dear ██████████

Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOIA), which was received by the Human Tissue Authority (HTA) on 25 March 2019. Your email outlined the following request:

Dear Sir/ Madam,

Under the Freedom of Information Act 2000 I would like to request the following information from the Human Tissue Authority.

In each of the individual calendar years: 2014, 2015, 2016, 2017 and 2018.

- 1) The number of umbilical cord blood units processed in the UK in each of the individual calendar years requested.
- 2) The number of umbilical cord tissue units processed in the UK in each of the individual calendar years requested.
- 3) The number of dental pulp units processed in the UK in each of the individual calendar years requested.
- 4) The number of organisations in the UK that the HTA wrote to warning them about compromised safety and quality standards in each of the individual calendar years requested.
- 5) The number of organisations in the UK that the HTA took regulatory action against in each of the individual calendar years requested.

I do not anticipate that my request for information will exceed Section 12 of the FOI Act, in terms of requiring the authority to spend more than 18 hours,

or costing the authority in excess of £450, to gather the information that I have requested.

In line with the FOI Act I anticipate a response to my request by 24th April 2019, taking into account two public holidays for Easter.

If you have any questions or queries about my request please do not hesitate to contact me at the earliest opportunity.

Kind regards,

Response

The following clarification has been provided regarding questions four and five of your request for information under the FOIA:

- You are requesting the number of establishments in the UK in relation to the activities referenced in questions 1 to 3, rather than for all of the establishments licensed by the HTA across all six sectors we regulate.
- Question 4 is in reference to major and critical shortfalls, but not minor ones.
- The “regulatory action” referred to in question five relates to Directions, Notices of Proposal (to vary a licence through conditions), Conditions, Suspensions, and Revocations.

Due to the timescales involved in seeking clarification, the deadline for responding was updated to 3 May 2019.

Please find below a table with the information requested:

Year	Number of umbilical cord blood units processed	Number of umbilical cord tissue units processed	Number of dental pulp units processed	Number of organisations receiving major or critical shortfalls on inspection		Number of organisations we took regulatory action against by type				
				Major	Critical	Directions	Notice of Proposal to vary a licence through Conditions	Conditions	Suspensions	Revocations
2014	15,040	6289	197	2	0	2	0	0	1	0
2015	14,847	7047	1893	1	1	2	2	0	0	0
2016	13,425	7595	310	0	0	0	0	0	0	0

2017	15,311	9847	553	4	0	0	0	0	0	0
2018	17,651	11,950	281	2	0	2	0	0	0	0

Please note, HTA standards are defined for each sector we regulate and are used by the HTA to assess the suitability of an establishment to carry on the licensed activity. It is mandatory for establishments in each sector to meet the standards. Where a standard is not met, the HTA will identify the shortfall and report the level of the shortfall to the establishment as critical, major or minor. The establishment will be required to produce a corrective and preventative action plan that details how they will address the shortfall(s) identified.

The HTA will assess progress towards addressing any shortfalls identified. If the HTA cannot confirm that appropriate corrective or preventative action has been taken to address a shortfall, the HTA may decide to take further regulatory action. There are several different types of regulatory action which may be considered; these include: variation of licences through the imposition of additional Conditions; the issuing of Directions; suspension or revocation of a licence.

You will see from the above table that a Notice of Proposal to vary a licence through Conditions will not always lead to Conditions being imposed. This will typically be due to the establishment rectifying the issue before the Conditions come into force.

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. There is no charge for making an appeal.

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

Yours sincerely



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