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Date: 10 June 2025

By email to: [redacted]

Dear [redacted]

Freedom of Information Act

Thank you for your email into the Human Tissue Authority (HTA) dated 08 May 2025 for which we gave the case reference number: [redacted] Your email has been handled as a request for information under the Freedom of Information Act 2000 ("**FOIA**").

Your email outlined the following request ("**your Request**"):

"Specifically for the Human Application sector, please provide:

1) The number of licence variations received in each of the last 5 years
2) Breakdown of the specific licensable activity variations for each year (i.e. number of procurement, distribution, processing etc)
3) For each year, the mean response time (in weeks) for authorisation of specific licensable activity variations, and the range of response times (in weeks)

4) The number of PPD submissions received in each of the last 5 years
5) For each year, the mean response time for authorisation of PPD submissions (in weeks), and the range of response times (in weeks)

6) The number of PPD amendments for existing authorised processes received in each of the last 5 years
7) For each year, the mean response time (in weeks) for approval of submitted amendments, and the range of response times (in weeks). "

Clarification

We sought further clarification on the scope of the request on 13 May 2025. We asked:

1. For question one, please clarify whether your request is limited to licence variations relating to the addition/removal of the following licensable activities to/from a licence: procurement, donor testing, processing, storage, distribution, import and export. If your request relates to other types of licence variation (such as change of DI, premises, addition of TPAs), please specify which types of licence variation you are seeking information about.
2. Please clarify if question four relates to the number of new PPDs submitted for authorisation by the HTA in each of the last five years (for information, the HTA considers both new PPDs and variations to be 'PPD submissions').

We received clarification on 13 May 2025. You confirmed that Question 1 relates only to addition/removal of the following licensable activities to/from a licence: procurement, donor testing, processing, storage, distribution, import and export. Also that Question 4 relates to new PPD submissions submitted for authorisation.

Response

Please find below the information requested in questions 1-3:

Year	Number of variations received	Number of Distribution variations	Number of Export variations	Number of Import variations	Number of Processing variations	Number of Procurement variations	Number of Storage variations	Number of Testing variations	Mean time for authorisation (weeks)	Range of authorisation times (weeks)
2020-21	17		9	3	3			2	5	1 - 33
2021-22	20	1	8	8		1		2	6	1 - 41
2022-23	14	3	3	3	2	1		2	4	1 - 20
2023-24	13	1	3	3	1	1	3	1	7	1 - 43
2024-25	18	3	6	1	1	4	2	1	3	1 - 32

Please note, the HTA is not able to provide information about mean response times for authorisation of individual licensable activity variations as many of the variation requests submitted to the HTA include multiple activities. The HTA is not able to split out individual authorisation times in such cases.

Please find below the information requested in questions 4 and 5:

Year	Number of new PPDs received	Mean response time (weeks)*	Range of response times (weeks)*
2020-21	11	3	1 - 5
2021-22	8	2	1 - 4
2022-23	11	3	1 - 7
2023-24	15	3	1 - 8
2024-25	9	1	1 - 2

* Responses can include authorisation, rejection or requests for more information. The HTA seeks more information about submitted PPDs in situations where the information provided by the establishment is insufficient to enable the HTA to make a decision about whether to authorise or reject the preparation process.

Please find below the information requested in questions 6 and 7:

Year	Number of PPD amendments received	Mean response time (weeks)**	Range of response times (weeks)**
2020-21	53	3	1 - 18
2021-22	44	2	1 - 9
2022-23	33	4	1 - 60
2023-24	27	3	1 - 12
2024-25	27	2	1 - 8

** Responses can include authorisation, rejection or requests for more information. The HTA seeks more information about PPD variation requests in situations where the information provided by the establishment is insufficient to enable the HTA to make a decision about whether to authorise or reject the variation.

Further information

We hope you found the above response to your Request clear and helpful. If you are unhappy with the way the HTA has handled your request for information in this case, or if you disagree with how we have interpreted FOIA in answering your Request, you may in the first instance ask us for an internal review by writing to us at the above postal or email address, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Any internal review of the HTA's handling of your information request will be reassessed by staff who were not involved in providing you

with this response.

Please remember to quote the case reference number above in any future communications.

If you remain dissatisfied after this internal review, 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,

Freedom of Information Officer