

By email to: [REDACTED]
[REDACTED]

Human Tissue Authority

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Date: 20 March 2025

Dear [REDACTED]

Freedom of Information Act

Thank you for your email into dated 11 March 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**"):

"For the 2024 calendar year please provide me with a table of Serious Adverse Events and Adverse Reactions in the organ donation and transplantation sector. Please could this table be provided in the same level of detail as that provided in a previous Fol response [Ref: 26 February 2015]. However, if there was an infection or disease transmitted to the recipient then please state what this disease or infection was."

Response

"The HTA holds information about Serious Adverse Events and Adverse Reactions (SAEARs) in the Organ Donation and Transplantation (ODT) sector.

The HTA routinely publishes quarterly reports, detailing the nature and volume of incidents reported, on its website: [Disclosing information on incidents | Human Tissue Authority](https://www.hta.gov.uk/about-the-HTA/transparency/disclosing-information-incidents) (<https://www.hta.gov.uk/about-the-HTA/transparency/disclosing-information-incidents>)

In reviewing the information you have requested we have noted that some of the information we hold is exempt from disclosure by virtue of the following exemptions:

Section 21

Information is absolutely exempt under Section 21 if it is accessible to the applicant by other means. Information in relation to SAEARs covering the 2024 calendar year

can be found on the disclosing information on incidents page on the HTA website:

[Q4 2023.24 ODT incidents details.xlsx](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2024-04%2FQ4%25202023.24%2520ODT%2520incidents%2520details.xlsx&wdOrigin=BROWSELINK)

(https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2024-04%2FQ4%25202023.24%2520ODT%2520incidents%2520details.xlsx&wdOrigin=BROWSELINK)

[Q1 2024.25 ODT incidents details.xlsx](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2024-10%2FQ1%25202024.25%2520ODT%2520incidents%2520details.xlsx&wdOrigin=BROWSELINK)

(https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2024-10%2FQ1%25202024.25%2520ODT%2520incidents%2520details.xlsx&wdOrigin=BROWSELINK)

[Q2 2024.25 ODT incidents details_0.xlsx](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2024-10%2FQ2%25202024.25%2520ODT%2520incidents%2520details_0.xlsx&wdOrigin=BROWSELINK)

(https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2024-10%2FQ2%25202024.25%2520ODT%2520incidents%2520details_0.xlsx&wdOrigin=BROWSELINK)

[Q3 2024.25 ODT incidents details.xlsx](https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2025-02%2FQ3%25202024.25%2520ODT%2520incidents%2520details.xlsx&wdOrigin=BROWSELINK)

(https://view.officeapps.live.com/op/view.aspx?src=https%3A%2F%2Fcontent.hta.gov.uk%2Fsites%2Fdefault%2Ffiles%2F2025-02%2FQ3%25202024.25%2520ODT%2520incidents%2520details.xlsx&wdOrigin=BROWSELINK)

If you have any difficulties in accessing this information at the source which I have provided, please contact me again.

Section 31

Section 31(1)(g) of the FOIA provides an exemption for “the exercise by any public authority of its functions for any of certain specified purposes”. Those specified purposes include the purpose of “ascertaining whether circumstances which would justify regulatory action in pursuance of any enactment exist or may arise”.

We have set out below the matters we have taken into account in considering where the balance of public interest lies concerning the release of information about SAEARs in the ODT sector.

- We acknowledge that there is a public interest in the HTA and how we fulfil our regulatory function, which includes the reporting of SAEARs in the ODT sector. We also acknowledge that there is public interest in having information about SAEARs in the ODT sector. We have therefore concluded that the public interest in disclosing that information outweighs the public interest in not disclosing that information.
- We have also considered where the balance of public interest lies in disclosing the information you have requested for individual incidents, including specific details of any potential disease or infection transmission.

- We have concluded that releasing all the information you have requested could have an adverse impact on the quality of reports supplied. The prospect of disclosure under FOIA is likely to result in a cautious and restrictive approach to SAEARs reporting, which could in turn be a risk to public safety.
- Establishments being deterred from providing detailed and frank reports by the prospect of disclosure would clearly prejudice our supervisory functions in relation to licensed establishments and would make it more difficult for us to establish whether formal regulatory action is required in specific cases.

Having reviewed the potential information we could release in response to your request for further details, we are satisfied that full disclosure of the detail in the reports is information which, if disclosed, would prejudice our ability to exercise our regulatory functions in supervising licensed establishments and investigating SAEARs.

We have therefore concluded that we will not disclose all of the information you requested; we believe that the public interest in disclosing some of that information does not outweigh the public interest in not disclosing that information.

The information for which we believe the balance of public interest in not disclosing outweighs the public interest in disclosing is as follows:

- precise detail of each individual SAEAR, including the identification of any disease or infection potentially transmitted.

We have therefore not disclosed this information in our response.”

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,

