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Date: 30 March 2023

By email to: [REDACTED]

Dear [REDACTED]

Freedom of Information request

Thank you for your Freedom of Information (FOI) request, which was received by the Human Tissue Authority (HTA) on Monday 06 March 2023. Your email outlined the following request:

“For the 2022 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.

SAEARs in the ODT sector must be reported under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 (as amended), referred to as the ‘Regulations’.

The Regulations define SAEARs in the ODT sector as follows:

- a) a serious adverse event (SAE) is ‘any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity’.

SAEs that may influence the quality and safety of an organ and that may be attributed to the testing, characterisation, procurement, preservation and transport of organs must be reported and investigated. The HTA also requires that any SAEs which occur at a transplant centre which may influence the quality and safety of an organ to be reported and investigated.

- b) A serious adverse reaction (SAR) is ‘an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity’.

SARs observed during or after transplantation which may be connected to the testing, characterisation, procurement, preservation and transport of organs must be reported and investigated.

The Regulations set out a number of functions that the HTA must undertake and allows the HTA to make arrangements for other organisations to assist us in carrying out these functions. NHS Blood and Transplant (NHSBT) manage the system for reporting and managing ODT SAEARs on behalf of the HTA as one of a series of assisted functions. Reports of ODT SAEs and SARs are made to NHSBT as part of their wider clinical incident reporting system.

NHSBT oversee the reports they receive and report all incidents that meet the definition of a SAE or SAR to the HTA. NHSBT notify the HTA of the steps being taken to manage the SAEAR and provide confirmation that all actions associated with the SAEAR have been concluded.

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 period January 2022 to December 2022 can be found on the ‘disclosing information on incidents page’ of the HTA website: <https://www.hta.gov.uk/about-hta/transparency/disclosing-information-incidents>

[Q3 2022/23 ODT incident details](#)

[Q2 2022/23 ODT incident details](#)

[Q1 2022/23 ODT incident details](#)

[Q4 2021/22 ODT incident details](#)

The HTA routinely publishes quarterly reports, detailing the nature and volume of incidents reported, on its website.

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 considerations we have taken into account in determining where the balance of public interest lies concerning the release of information about SAEARs in the ODT sector.

Disclosing 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 and investigation 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 pertaining to 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 provided to the HTA. 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 discouraged 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

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, 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.org.uk

Yours sincerely

