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Date 20 March 2020

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 3 March 2020. Your email outlined the following request:

Can you please provide the current up to date list of Disease Testing Requirements for Blood Donors in the UK, including the minimum requirements as set out by the 2004/33/EC Directive, or, if said directive has been superseded, by the current directive in place, covering the same.

To be clear, I am looking for the most up to date list, including all blood and blood product transmissible pathogens (bacterial, parasitic, viral and fungal), covering their specific national requirement for testing, as outlined below.

- a) Absolute minimum testing requirements, (in accordance with my opening paragraph)
- b) Testing which is legally binding on a national level
- b) Testing which is recommended, but not legally binding on a national level
- c) List of pathogens, (bacterial, parasitic, viral and fungal), the testing of which is neither legally binding or recommended on national level

In light of the HTA 2015 Mapping Exercise, which recommended more stringent blood donor testing requirements, can you please provide information on changes implemented over the intervening years and any other information relevant to this.

Response

The HTA's remit does not extend to the regulation of blood donations; in the UK, this function is performed by the Medicines and Healthcare products Regulatory Agency (MHRA). Therefore, we are unable to provide the information you have requested as it is not held by us.

The HTA regulates organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. We also give approval for organ and bone marrow donations from living people.

The HTA did not conduct a mapping exercise in 2015 recommending more stringent blood donor testing requirements. In that year, the HTA contributed data to an EU survey of the testing requirements for donors of tissues and cells; information about that survey can be found here -

https://ec.europa.eu/health/blood_tissues_organs/key_documents/testing_blooddonors_mapping_en

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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