

**Human Tissue Authority**  
151 Buckingham Palace Road  
London  
SW1W 9SZ

By email to [REDACTED]

**Tel** 020 7269 1900  
**Web** [www.hta.gov.uk](http://www.hta.gov.uk)  
**Email** [enquiries@hta.gov.uk](mailto:enquiries@hta.gov.uk)  
**Date** 6 August 2020

Dear [REDACTED]

## **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 10 July 2020. Your email outlined the following request:

I wish to make a freedom of information request regarding human tissue imported for the use in medical research and medicines. How many, if any, cases of imported human body tissue for use in medical research or medicines, have been successfully imported from the People's Republic of China to the UK since 2010?

If there has been any cases of the above, please provide a breakdown such as; tissues, blood products, plasma etc.

## **Response**

### ***Human tissue imported for use in medicines***

We hold a subset of the information that you have requested.

When tissues and cells are imported from third countries for use in the manufacture of advanced therapy medicinal products, this must be carried out under a HTA Human Application licence under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended) (the Q&S Regs). This licensing requirement does not extend to the import of part manufactured, or manufactured medicines; this activity falls within the remit of the Medicines and Healthcare products Regulatory Agency (MHRA).

Since 2018, no human tissue or cells have been imported from the People's Republic of China by establishments licensed in the Human Application sector.

Prior to 2018, we did not keep records of the country of origin for tissues or cells imported under the Q&S Regs. Establishments themselves were required to maintain full inventories and traceability data which we review in the course of carrying out our regulatory activities.

### ***Human tissue imported for use in medical research***

We do not hold the data you have requested.

The HTA's regulatory remit is defined in the Human Tissue Act 2004 (HT Act). Human tissue for use in research *in vitro*, that will not be transplanted into humans, is regulated under the HT Act. The import and export of relevant material is not a licensable activity under the HT Act. However, the storage of the material once it is imported may be licensable if this is for a scheduled purpose, such as research within the scope of the HT Act.

In the course of our regulatory activities, we may receive some details of imported material but we do not seek to maintain records of material held by the establishments that we license; establishments themselves maintain full inventories of the material they hold.

### **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](http://www.ico.gov.uk)

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