Human Tissue Authority

2nd Floor
2 Redman Place
London
E20 1JQ

Tel: 020 7269 1900
Web: www.hta.gov.uk
Email: enquiries@hta.gov.uk

Date: 30 March 2022

By email to: [redacted]

Dear [redacted]

Freedom of Information request

Thank you for your request for information under the Freedom of Information Act (FOI Act), which was received by the Human Tissue Authority (HTA) on Wednesday 16 February 2022. Your email outlined the following request:

"Dear Human Tissue Authority

We make this request under the Freedom of Information Act 2000.

Please can you provide the following information:

1. Please confirm whether the following entities hold a licence under the Human Tissue (Quality Safety for Human Application) Regulations 2007 (the "**2007 Regulations**"):
    - Ancestry.com
    - Ancestry.com Operations Inc
    - Ancestry.com DNA LLC
    - Ancestry International DNA, LLC
    - Ancestry Ireland Unlimited Company
    - 23andMe Inc
    - Circle
    - Prenetics EMEA Limited
    - DNAfit Life Sciences Limited
2. For entities where no licence is held, please confirm whether the Human Tissue Authority (the "**Authority**") has had any communication or correspondence in relation to the application of the 2007 Regulations, the Human Tissue Act 2004 (the "**Act**") or the Authority's jurisdiction.
3. Please provide non-confidential copies of all correspondence that respond to our request 2.
4. In relation to the entities identified in our request 1 and where a licence is held, please confirm whether the Authority has taken any action in relation to concerns or breaches or suspected breaches of the 2007 Regulations or the

Act. Please identify the relevant entities that have been subject to such action and the basis of the Authority's concern.
5. Please provide non-confidential copies of all correspondence that respond to our request 4."

Clarifications

On Wednesday 02 March 2022, you provided clarification about your request for information:

"The relevant period for the search can be limited to Jan 2013 onward."

On Friday 04 March 2022, you provided final clarification about your request for information:

"By "non-confidential" we mean that the Authority may wish to redact information which is, for example, personal data or otherwise confidential to a party."

Response

1. None of the entities hold a HTA licence.

   Please note that the HTA publishes the names of HTA-licensed establishments on our website.

   (https://www.hta.gov.uk/professional/establishments)

2. We confirm that we do hold information within the scope of this request.

3. Information within the scope of request 3 is provided in an appendix to this letter.

   Some information has been redacted in line with the scope of the information request, in accordance with relevant exemptions set out in the Freedom of Information Act 2000 and following the redaction guidance set out in the HTA's applicable corporate document.

   The lawful exemption relied on in this response is section 40.

   Section 40 provides an exemption for information which constitutes the personal data of a third party and disclosure would breach any of the data protection principles. In this case, we have withheld information which relates to identifiable individuals and so constitutes personal data as defined in the General Data Protection Regulation (**GDPR**), and disclosing it would be unlawful and unfair, therefore breaching the data protection principles contained in the GDPR. Where possible, we have simply redacted the names

of individuals to disguise their identities. However, we have also needed to redact additional information which could be used to identify those individuals.

4. Not applicable – please see our response to request 1.

5. Not applicable – please see our response to request 4.

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

Gisela Amabilino
Corporate Service Manager

[redacted]

From: [redacted]
Sent: 09 October 2014 16:43
To: [redacted]
Subject: Fw: 23andMe plans for UK Launch- Confidential

Follow Up Flag: Follow up
Flag Status: Flagged

Hello [redacted]

This is the email from [redacted] - it would be good to respond by Monday lunchtime.

Thanks.

[redacted]
Human Tissue Authority
[redacted]

From: [redacted]
Sent: Thursday, October 09, 2014 09:18 AM GMT Standard Time
To: [redacted]
Cc: [redacted]
Subject: RE: 23andMe plans for UK Launch- Confidential

Dear [redacted],

Thanks for forwarding this. We have been in contact with 23andme over a number of months and together with MHRA are due to meet next week to discuss their plans and any remaining questions we have.

In summary, the regulatory landscape here is very different from the FDA's approach in the US and MHRA are working on the basis that they can self-certify their collection kits and patient information. This might change in the future but for now we have no pre-market approval process. There may be other regulatory issues – of which HTA is an example – but we have simply put them in touch with a number of other bodies.

It would be helpful if you could keep me posted on any response, I am due to meet them next week (14th I think) and will keep you in the loop.

Regards

[redacted]

Department of Health

[redacted]
Department of Health, 79 Whitehall, SW1A 2NS
[redacted]

From: [redacted]
Sent: 09 October 2014 08:07
To: [redacted]
Cc: [redacted]
Subject: Fw: 23andMe plans for UK Launch- Confidential

[redacted]

Information or advice for [redacted]?

[redacted]

From: [redacted]
Sent: Thursday, October 09, 2014 07:47 AM GMT Standard Time
To: [redacted]
Subject: Fw: 23andMe plans for UK Launch- Confidential

Hello [redacted]

I guess this is on your radar but thought I would let you know about the direct contact.

Is there any further information you can share that would be relevant to us?

Thanks.

[redacted]
Human Tissue Authority
[redacted]

From: [redacted]
Sent: Wednesday, October 08, 2014 05:27 PM GMT Standard Time
To: [redacted]
Cc: [redacted]
Subject: 23andMe plans for UK Launch- Confidential

Dear [redacted]

I hope you are well. I am writing to you on behalf of 23andMe – a US company which offers a saliva-based, easy-to-use and affordable Personal Genome Service (PGS) which identifies variants in medically-relevant genes and returns the results of these tests to users.

My reason for writing is to notify you that the company is planning to be launch our PGS in the UK, the exact timing of our launch has not been determined and our planning process is confidential. We anticipate that this launch - the first of a personal, DNA service which is accessible to the vast majority of the population – will have a big impact, not just on those who make use of the service, but also on the whole life sciences sector. PGS users will receive genetic information about 104 common carrier diseases, traits,

genetic risk factors for various health conditions – and information about their ancestry. The life sciences sector will be able, over time, to gain access to our growing database of pseudonymised genetic information – supporting the UK research industry and the wider UK economy.

We are working hard to address questions all those with an interest in PGS have about our service ahead of its launch, and are being guided in everything we do by the framework on genetic testing developed by the Government's Human Genetics Commission. We have discussed our launch in the UK in detail with the Department of Health, the NHS and the MHRA – and are continuing to liaise with them on an ongoing basis.

Although our legal advice indicates that there is no need to apply for a licence from the Human Tissue Authority (HTA) at this stage – given that the samples we collect from PGS users are held for a brief period in the UK before transfer to labs in the US – we are nonetheless eager to open a discussion with you. We see the UK very much as a future base of our operations, and want to ensure that you are sighted on the long-term plans we have to locate our services in the country and to make clear our standing offer to the HTA to answer any questions you have as and when they arise.

I do hope you might be able to find some time to meet in the near future. My colleagues and I are in the UK frequently, and my local advisors at Incisive Health will be in touch with you shortly to see whether you might have time to meet when I am next scheduled to be in London. In the meantime, do please let me know if you have any questions.

Yours sincerely,

[redacted]

23andMe

[redacted]

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[redacted]

From: [redacted]
Sent: 14 October 2014 10:35
To: [redacted]
Cc: [redacted]
Subject: RE: 23andMe plans for UK Launch- Confidential

Follow Up Flag: Follow up
Flag Status: Flagged

Dear [redacted]

Thank you for contacting the HTA and for keeping us informed of developments with your company. In summary, you are correct that there is no need for you to apply for a licence from the HTA at present, as outlined below. If your arrangements change from what have been proposed, please contact us again for further advice.

Based on the information you have given us we can provide the following advice on the requirements of the Human Tissue Act 2004 (the HT Act) and related legislation.

Our advice is based on the assumption that all material for testing will be taken from the living, and only stored in the UK for a short period of time prior to transport to the US for analysis. If testing is to be carried out on material from the deceased then different regulatory requirements will apply and 23andme should contact us for further advice prior to any material being removed.

It is useful to consider both the consent and licensing requirements of the HT Act. For the purposes of the HT Act, saliva is considered to be both 'relevant material' and 'bodily material'. The genetic analysis described would constitute the scheduled purpose of 'obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)'.

Consent

Consent is the fundamental principle which underpins the HT Act.

Under the HT Act, consent is required for the storage and use of 'relevant material' for the scheduled purpose outlined above. To carry out this activity without consent would be unlawful and an offence under the HT Act. Additionally, it is also an offence under section 45 of the HT Act to have any 'bodily material' with the intention to analyse DNA without qualifying consent.

Further information on what constitutes appropriate consent can be found in our Code of Practice:
http://www.hta.gov.uk/_db/_documents/Code_of_practice_1_-_Consent.pdf

As the company intend to make the results of the DNA analysis available to other parties in the future, potentially for research, we would strongly recommend that this aspect was addressed explicitly in the consent procedure. Furthermore, it would be advisable to explain to donors the implications of analysis in order that they are aware of the nature of the information that might be provided by such analysis. In such circumstances we would recommend that consent was both generic and enduring – again, further information can be found in our Code of Practice documents.

Licensing

The HT Act requires licensing of the removal and storage of 'relevant material' for a number of scheduled purposes, although there are several exceptions.

A removal licence is not required to remove 'relevant material' from a living person.

A storage licence is not required to store 'relevant material' from the living for 'obtaining scientific or medical information about a living or deceased person which may be relevant to any other person'.

In general a licence to store material is required for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'; however it is not clear from the information provided whether the future use of the results of the DNA analysis by third parties would fall under this scheduled purpose. In any case, a licence is not required where the storage is 'incidental to transportation' as is described your email. Current HTA guidance is that this should be for no longer than 7 days.

I hope you find the above useful. Please do not hesitate to contact us if you require anything further.

Kind regards

[redacted]

[redacted]
Human Tissue Authority
[redacted]

From: [redacted]
Sent: 08 October 2014 17:27
To: [redacted]
Cc: [redacted]
Subject: 23andMe plans for UK Launch- Confidential

Dear [redacted]

I hope you are well. I am writing to you on behalf of 23andMe – a US company which offers a saliva-based, easy-to-use and affordable Personal Genome Service (PGS) which identifies variants in medically-relevant genes and returns the results of these tests to users.

My reason for writing is to notify you that the company is planning to be launch our PGS in the UK, the exact timing of our launch has not been determined and our planning process is confidential. We anticipate that this launch - the first of a personal, DNA service which is accessible to the vast majority of the population – will have a big impact, not just on those who make use of the service, but also on the whole life sciences sector. PGS users will receive genetic information about 104 common carrier diseases, traits, genetic risk factors for various health conditions – and information about their ancestry. The life sciences sector will be able, over time, to gain access to our growing database of pseudonymised genetic information – supporting the UK research industry and the wider UK economy.

We are working hard to address questions all those with an interest in PGS have about our service ahead of its launch, and are being guided in everything we do by the framework on genetic testing developed by the Government's Human Genetics Commission. We have discussed our launch in the UK in detail with the Department of Health, the NHS and the MHRA – and are continuing to liaise with them on an ongoing basis.

Although our legal advice indicates that there is no need to apply for a licence from the Human Tissue Authority (HTA) at this stage – given that the samples we collect from PGS users are held for a brief period in the UK before transfer to labs in the US – we are nonetheless eager to open a discussion with you. We see the UK very much as a future base of our operations, and want to ensure that you are sighted on the long-term plans we have to locate our services in the country and to make clear our standing offer to the HTA to answer any questions you have as and when they arise.

I do hope you might be able to find some time to meet in the near future. My colleagues and I are in the UK frequently, and my local advisors at Incisive Health will be in touch with you shortly to see whether you might have time to meet when I am next scheduled to be in London. In the meantime, do please let me know if you have any questions.

Yours sincerely,

[redacted]

[redacted]

23andMe

[redacted]

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[redacted]

From: [redacted]
Sent: 02 December 2014 16:06
To: [redacted]
Cc: [redacted]
Subject: RE: 2014.12.02 DNA Profiling Services

Follow Up Flag: Follow up
Flag Status: Flagged

Hi [redacted],

They have been in touch with us and you're right, for a number of reasons, the regulatory requirements don't apply. We will be keeping an eye on it though.

[redacted]

[redacted]
Human Tissue Authority
151 Buckingham Palace Road
Victoria
London SW1W 9SZ
[redacted]
Web www.hta.gov.uk

From: [redacted]
Sent: 02 December 2014 16:00
To: [redacted]
Subject: 2014.12.02 DNA Profiling Services
Importance: Low

[redacted]

You may have notices reports that an organisation 23andMe has started offering its DNA profiling services to the public in the UK. Notably the organisation was recently prevented from marketing services in the USA by the Federal Drug Administration.

The organisation's site is at

https://www.23andme.com/en-gb/

It is also interesting to note that the consent document seems to give them the right to use the information generated for research. See:

https://www.23andme.com/en-gb/about/consent/

The site suggests all analysis is done in the USA. I am guessing the samples are taken by individuals and posted directly to the USA. That would probably avoid most of the regulations in the UK.

Best wishes

[redacted]

[redacted]
Home Office Science

Home Office
5 St Philip's Place, Colmore Row, Birmingham, B3 2PW
[redacted]

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[redacted]

From: [redacted]
Sent: 01 October 2014 15:33
To: [redacted]
Cc: [redacted]
Subject: RE: https://www.23andme.com/ coming to the UK

Follow Up Flag: Follow up
Flag Status: Flagged

Dear All

Thanks a lot, very helpful as always. I will see if I can get any further information from them.

[redacted]

Department of Health

[redacted]
Health Science and Bioethics,
[redacted] Richmond House, 79 Whitehall, SW1A 2NS
E: [redacted]

From: [redacted]
Sent: 01 October 2014 14:36
To: [redacted]
Cc: [redacted]
Subject: RE: https://www.23andme.com/ coming to the UK

Hi [redacted],

I suppose the important bits of information are to do with what material is to be stored and used (in or outside E/W/NI), what purposes cellular tissue might be stored for (and whether any of these would be purposes covered by the Act e.g. research in connection with functioning or disorders of the human body) and whether cellular tissue is from the living or the deceased.

We have had enquires about companies wishing to screen living people for genes linked to disease (so health screening not research), so the following Q&As might be relevant.

If [redacted] can send us a summary of what [redacted] understands the company are hoping to set up, we can provide a tailored set of answers (thanks, [redacted]).

There are so many contortions and exceptions in the Act, it would be helpful to just have the specifics to work with!

I think if they are planning to offer only health screening or 'interesting ancestry' for consenting adults, there might not be much for us; however, if FDA have had concerns, I can understand why there is interest. I note from their website that they have been successful in achieving NIH-funded research in the US so that appears reassuring at first glance.

I've copied in [redacted], too, as [redacted] has done quite a lot of work around the DNA requirements.

Thanks,

[redacted]

1. **Is the genetic testing carried out by private companies regulated only by HTA? What other public offices, regulators or any other institutions deal with genetic testing?**

Health screening of living people is outside of the licensing remit of the HTA. In the UK, health screening is typically offered by NHS or private health facilities. We would suggest that you contact the Department of Health to confirm any requirements as we cannot advise you on this.

2. **What purposes of the genetic testing would require licence from the HTA?**

Please refer to the answer to question 1.

Please note that the removal and/or storage of human material from deceased people for the purpose of 'Obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person)' (or for another of the Act's 'scheduled purposes') would typically require to be licensed by the HTA. As I remarked earlier, we'd be happy to advise further if this is relevant to the proposed activities.

3. **What is the maximum period of storage of the samples which does not require licence of the HTA?**

Please refer to the answer to question 2.

In cases where licensable storage is required (see above), the Act does not give any minimum of maximum term for storage.

4. **Is it legal to test gens BRCA1 and BRCA2 in the UK?**

We understand such testing currently already takes place in the UK.

5. **Do I understand correctly that in order to carry out the collection of samples and genetic testing in the UK, a private company needs only a consent of the person whose tissue it is and not any consent, act or decision of any other public body or institute?**

Please refer to the answers to questions 1 and 2.

6. **Does the private company need to register itself with or inform the HTA or any other public body or institute that it collects samples in the UK?**

   Please refer to the answers to questions 1 and 2.

We cannot advise on requirements for private companies wishing to provide health screening in the UK.

7. **Are there any activities associated with collecting the samples in the UK (such as transport of the samples on the territory of the UK and across the UK borders, employment of people taking the samples, operating premises where the samples are taken, etc) which requires license, consent or permission of the HTA or any other public office or institution?**

Please refer to the answer above.

We also provide a code of practice on the import and export of human bodies, body parts and tissue. This Code indicates appropriate practice for HTA-licensed establishments. However, in addition, it sets out good practice for individuals and establishments not undertaking licensable activities under the Act but nonetheless involved in the import and export of human bodies, body parts and tissue used for other purposes.

[redacted]
Human Tissue Authority
151 Buckingham Palace Road
London SW1W 9SZ
[redacted]

From: [redacted]
Sent: 01 October 2014 13:39
To: [redacted]
Cc: [redacted]
Subject: https://www.23andme.com/ coming to the UK

HI [redacted] from DH rang me to say that this company was setting up in the UK https://www.23andme.com/
to deliver ancestry testing and health reporting. [redacted] is off to States to meet them.
I understand they were banned by FDA in the US I think from the perspective of health reporting. [redacted] would like to understand the potential requirements. Can you get back to [redacted] and keep us in the loop?
If operating in UK, they may have to have an HTA licence depending on whether they store tissue/saliva or just DNA, and also what are the requirements around consent?
Thanks in advance
[redacted]

[redacted]

Human Tissue Authority
151 Buckingham Palace Road, London, SW1W 9SZ
[redacted]

Please note: [redacted]

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