Department of Health & Social Care

Freedom of Information Team
Department of Health and Social Care
39 Victoria Street
London SW1H 0EU

www.gov.uk/dhsc

Ms Linda Birr-Pixton
By email to: request-1178647-9e736283@whatdotheyknow.com

23 October 2024

Dear Ms Birr-Pixton,

Freedom of Information Request Reference FOI-1534130

Thank you for your request dated 25 September to the Department of Health and Social Care (DHSC), a copy of which can be found in the accompanying annex.

Your request has been handled under the Freedom of Information Act 2000 (FOIA).

DHSC does not hold any information relevant to your request.

With reference to your question about guidance to the Medicines and Healthcare products Regulatory Agency (MHRA), DHSC has not issued any advice or guidance to the MHRA on this issue. With reference to research generally, the DHSC (through its research arm, the National Institute for Health Research (NIHR)) does not engage in any pre-human research and development, so does not hold any information relating to research involving animals or animal tissue.

You may be aware that the use of animals in experiments and testing is regulated under the Animals (Scientific Procedures) Act 1986 (ASPA). A section of the Home Office (The Animals in Science Regulation Unit) is responsible for administration and enforcement of ASPA. More information about that unit is available at the following link: Animals in Science Regulation Unit - GOV.UK. If you should wish to submit a request under the FOIA to the Home Office, it can be contacted at: foirequests@homeoffice.gov.uk

You may also be interested in the following information, which we are providing on a discretionary basis. This is outside of the scope of the FOIA, and not subject to internal review.

The MHRA has advised us of the following. The relevant guidelines that the MHRA refers to on medicinal product development are those of the International Conference on Harmonisation (please see https://www.ich.org/page/ich-guidelines), the World Health Organisation (please see https://www.who.int/publications/m/item/annex1-nonclinical.p31-63) and other international regulatory bodies (e.g. the US Food and Drug Administration and the EU European Medicines Agency) as well as a small number produced by the MHRA itself.

If you have any follow up questions with reference to the above, we suggest that you may wish to contact the MHRA. Requests under the FOIA can be submitted to the MHRA at info@mhra.gov.uk

If you are not satisfied with the handling of your request, you have the right to appeal by asking for an internal review. This should be sent to freedomofinformation@dhsc.gov.uk or to the address at the top of this letter and be submitted within two months of the date of this letter.

Please remember to quote the reference number above in any future communication.

If you are not content with the outcome of your internal review, you may complain directly to the Information Commissioner's Office (ICO). Generally, the ICO cannot make a decision unless you have already appealed our original response and received our internal review decision. You should raise your concerns with the ICO within three months of your last meaningful contact with us.

Guidance on contacting the ICO can be found at https://ico.org.uk/global/contact-us and information about making a complaint can be found at https://ico.org.uk/make-a-complaint.

Yours sincerely,

Freedom of Information Team
freedomofinformation@dhsc.gov.uk

Annex

From: Linda Birr-Pixton <request-1178647-9e736283@whatdotheyknow.com>
Sent: Wednesday, September 25, 2024 10:43 AM
To: FreedomofInformation <freedomofinformation@dhsc.gov.uk>
Subject: Freedom of Information request - Performance assessments on 21st century technology

Dear Department of Health and Social Care, I read with interest the recent UK government press release announcing a £400 million public-private collaboration launched to kickstart economic growth and build an NHS fit for the future.

Can you please refer me to the advice and guidance you have provided to the MHRA with regard to the continuing use of unreliable animal tests as the back bone of pre-clinical studies by pharmaceuticals?

According to the US Food and Drug Administration, out of ten drugs that successfully pass animal tests, nine will fail during clinical trials, either as a result of adverse reactions not seen in the animals or else due to lack of efficacy in humans.

What has the Department of Health and Social Care provided as advice and indeed regulation to ensure that the the availability of modern technologies that far surpass animal tests in terms of reliability and relevance to human health such as Liver on a chip is now one of the key and expected tools in preclinical studes.

As one example, the human « liver on a chip » is far more reliable than animal tests at detecting drug induced liver injury (DILI for short). This is hugely significant because the « liver on a chip » will prevent dangerous drugs from ever reaching clinical trials, whereas animal testing is notoriously unreliable at detecting and predicting DILI.

Not only is DILI the leading cause of prescription drug withdrawal from the market, but such liver damage can even result in a patient requiring a liver transplant.
One single liver transplant costs the NHS around £ 121 000.

I attach these articles which have informed my request for information
https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nature.com%2Farticles%2Fs43856-022-00209-1&data=05%7C02%7Cdhmail%40dhsc.gov.uk%7Cb679c669f96c4bc9afc308dcdd6da4e1%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C638628710198621497%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=k03ZnJKQAoLAYz0MPjwTMLG%2Bq%2BWnNtZr17S1aA2QErw%3D&reserved=0

https://eur03.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.nature.com%2Farticles%2Fs41573-021-00323-0&data=05%7C02%7Cdhmail%40dhsc.gov.uk%7Cb679c669f96c4bc9afc308dcdd6da4e1%7C61278c3091a84c318c1fef4de8973a1c%7C1%7C0%7C638628710198637666%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C0%7C%7C%7C&sdata=DZBAQVknQrmsnkxaepvxcZDmndcPK9MHrlYrlaQxI3Y%3D&reserved=0

Adoption of organ-on-chip platforms by the pharmaceutical industry | Nature Reviews Drug Discovery.

Can you point me to the information that is being used to not allow the implementation of the use of the Liver on a chip as a part of the pre-clinical toolkit for researchers and drug development and is this a general omission or a specific one with regard to the use of non animal methods?

Yours faithfully,

Linda Birr-Pixton