Medicines & Healthcare products
Regulatory Agency

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[redacted]
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24 May 2024

MHRA reference: FOI2024/00074

Dear [redacted],

Thank you for your information request, which we received on 29 April. You asked for:

> *1. How does the MHRA currently consider data obtained from human organs on chips as a valid source of information when evaluating a new drug application from a pharmaceutical manufacturer?*
> *2. How is that information made available by the manufacturer to the MHRA and vice versa?*
> *3. How is that information made available to the public particularly those intending to participate in clinical trials and before signing informed consent forms?*
> *4. What plans are being put into place to use organs- on a chip particularly the liver on a chip as an important contribution to patient safety and can you direct me to them if they are already published? If they are not published when can I expect to see them published?*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

We confirm that MHRA holds information that is relevant to your request. We will respond to each of your questions below:

1. How does the MHRA currently consider data obtained from human organs on chips as a valid source of information when evaluating a new drug application from a pharmaceutical manufacturer?

   In terms of how the MHRA considers these data, the MHRA employs assessors who review reports provided by the developer and apply their scientific judgement to gauge aspects such as scientific credibility, relevance of testing and the basis of conclusions made from these studies, as part of an overall assessment on the quality, safety and efficacy of the product.

2. How is that information made available by the manufacturer to the MHRA and vice versa?

   Information from manufacturers is made available through the submission of the electronic Common Technical Document (eCTD) that is submitted to MHRA. Module 4 of the eCTD in particular contains the data collected from non-clinical studies, which could include data from this type of technology.

3. How is that information made available to the public particularly those intending to participate in clinical trials and before signing informed consent forms?

   The relevant Ethics Committee and the Health Research Authority (HRA) review and decide on the information to be made available to the participants/patients who may wish to participate in a clinical trial when a Clinical Trial Authorisation submission is compiled.

   Further information on this can be found on the HRA website, a link to this is provided below:
   Publishing your research findings - Health Research Authority (hra.nhs.uk)

4. What plans are being put into place to use organs- on a chip particularly the liver on a chip as an important contribution to patient safety and can you direct me to them if they are already published? If they are not published when can I expect to see them published?

   The MHRA supports the use of alternatives to animals in development of novel medicines and can give developers bespoke scientific advice on this topic in its scientific advice service. However, the MHRA does not develop novel medicines itself, but rather regulates those who do and it is for developers to use the most appropriate testing methodology for their products. MHRA staff also engage with organisations, such as the National Council for 3Rs, the European Organ-on-chip Society (EUROoCS) and the Medical Research Council, supporting these organisations in their endeavours to promote use of technologies such as cell-based assays or organs-on-a-chip.

   MHRA will not publish the engagement with industry on this topic. However, any marketing authorisations that are granted by MHRA that use this technology will have Public Assessment Reports (PARs) published that will explain the assessment of the non-clinical data obtained using this technology.

We hope this information is useful for you.

This concludes our response to your request.

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If you have a query about this response, please contact us at foi.request@mhra.gov.uk.

Please remember to quote the reference number at the top of this letter in any future communications. Details of your appeal rights are below.

Yours sincerely,

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Appeal rights
If you are dissatisfied with the handling of your request, you can ask us to conduct an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at: https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/

Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF

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