Medicines & Healthcare products
Regulatory Agency

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[redacted]
By email: request-1061139-9cb53fdd@whatdotheyknow.com

17 January 2024

FOI **23/984**

Dear [redacted]

Thank you for your request under Freedom of Information, dated 17 December 2023.

Your request:

> "This topic was endorsed by the ICH Assembly in June 2019.
> The ICH S12 Guideline reached Step 4 of the ICH process on 14 March 2023.
> The ICH S12 Guideline:
> Provides harmonised recommendations for the conduct of nonclinical biodistribution (BD) studies in the development of gene therapy (GT) products; Includes recommendations to facilitate the development of GT products while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles; Makes recommendations for the overall design of nonclinical BD assessments.
> Date of Step 4:
> 14 March 2023
> Status: Step 5
> Implementation status:
> ANVISA, Brazil - In the process of implementation; EC, Europe - Implemented; Date: 30 September 2023; Reference: EMA/CHMP/ICH/318372/2021 EDA, Egypt - Not yet implemented; FDA, United States - Implemented; Date: 4 May 2023; Reference: 88 pg. 28565-28566 Health Canada, Canada - Implemented; Date: 21 July 2023; Reference: File #:20-109241-111 MFDS, Republic of Korea - In the process of implementation; Date: 30 November 2024; MHLW/PMDA, Japan - Implemented; Date: 23 October 2023; Reference: PSB/MDED Notification No. 1023-1 MHRA, UK - Not yet implemented; NMPA, China - Implemented; Date: 5 September 2023; Reference: NMPA, China Announcement No. 115(2023) Swissmedic, Switzerland - Implemented; Date: 14 March 2023; TFDA, Chinese Taipei - In the process of implementation;

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Can you tell me when the this guideline is being implemented in the UK? If it is not going to be implemented, can I see the documentation explaining the rationale for non implementation? What has the MHRA provided to research laboratories and places of research on this issue in terms of information and may I see it please?"

Our responses (for ease of reading/reference we have numbered your questions):

1. **Can you tell me when the this [sic] guideline is being implemented in the UK?**

Background:

The MHRA are planning to implement Guideline ICH S12 Nonclinical biodistribution considerations for gene therapy products, in the intervening time we are considering how the guideline aligns with our domestic expectations of developers and asking developer if and how they have taken the guideline into account.

In General, the MHRA expects developers to take note of guidelines where these are in the public domain even if they are not yet formally adopted. The MHRA offers regulatory or scientific advice to developers and has scores of such meetings every year. One component of these advice procedures can include for developers to consider relevant published guidance and obtain assistance from MHRA on how guidance might be applied in relation to the specific product in question.

Response to meet Section 1(1) a of FOIA.
We do not hold any information on a specific date/time when this guideline will be implemented in the UK. However, it will be implemented at some point in the future.

2. **If it is not going to be implemented, can I see the documentation explaining the rationale for non implementation?**

Our answer to this question is negative, due to the intention that the guideline will be implemented.

3. **What has the MHRA provided to research laboratories and places of research on this issue in terms of information and may I see it please?**

Response to meet Section 1(1) a of FOIA.
We hold no information related to this question and we have no plans to provide any further information to research laboratories at present, with regards to the guideline.

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If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

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

If you were to remain dissatisfied with the outcome of the internal review, you would 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Yours sincerely,

FOIA Team

MHRA Customer Service