

FOI 23-383 – guidance on use of ICH guideline S1B(R1) on testing for carcinogenicity of pharmaceuticals

REQUEST

25 May 2023

The above guideline was made effective from 16th March 2023.

Could you please provide me with the following information:

1. What guidance has been provided and is going to be provided with regard to the use of this guideline for research purposes in the UK?
2. How will you ensure that this guidance is provided to existing project licence holders to update their methodology to encompass regulatory guidelines with regard to testing for carcinogenicity of pharmaceuticals.

MHRA RESPONSE

15 June 2023

Dear

Thank you for your email.

The MHRA does not intend to issue any additional standalone guidance on the revision of ICH guideline S1B on testing for carcinogenicity of pharmaceuticals. It is the responsibility of companies to keep abreast of changes in relevant guidance and take the current effective version into account when designing non-clinical studies to support the development of medicinal products.

The Home Office, not the MHRA, is responsible for issuing licences that are required by the Animals (Scientific Procedures) Act 1986. The MHRA do not hold any information on project licences or project licence holders.

Interested parties can seek scientific advice from the MHRA in relation to all aspects of medicinal product development. As part of this service, the MHRA takes every opportunity to draw attention to relevant adopted guidance and make recommendations on planned non-clinical studies and overall non-clinical development strategies, taking into account the 3 Rs principles (refinement, reduction and replacement).

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

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