Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

30th January 2024

Dear [redacted]

FOI 23/1016

Thank you for your request of 31 December 2023, under the Freedom of Information Act. Your request is stated below, and the response covers the two aspects of your question.

Dear Medicines and Healthcare Products Regulatory Agency,
On the 17th October 2023, in reply to a question in the Commons, the MP for Colchester, replied on behalf of the Government to a question about the use of Non Animal Methods of Testing expertise. This question was related to the making of judgements on the methodology of validation and the role of the Non-Clinical Assessors.
Having now read the recent curriculum vitae for both Non Clinical Assessor posts advertised, my first question is how has the Agency resolved the issue of appropriate expertise in judging the data provided when the Non Clinical Assessors do not appear to have any experience or expertise in Non Animal methods according to the published Job specification and curriculum vitae?
My second question relates to the advice the MHRA is providing by it's offer of scientific advice services. Given the MHRA is promoting the 3R's, it is clearly aware of the 1986 ASPA and amendments. By law the MHRA is obliged to abide that this law.
The law at Section 2A (2) (a)is clear that a scientifically satisfactory method or testing strategy not entailing the use of protected animals must be used instead of a regulated procedure. The responsibility for this lies with the MHRA as a Government Agency as much as the individual or organisation seeking to have their products validated.
Please explain how the MHRA is fulfilling that obligation as I am unable to see any reference to this issue on any published information by yourselves.

With respect to the first part of your question, non-clinical assessors review all in silico, in vitro and in vivo data presented by applicants/sponsors in support of marketing authorisation or clinical trial applications. Data from a suitably validated in silico or in vitro models that have been demonstrated to be predictive can be submitted in lieu of animal data. In addition, where possible, non-clinical assessors will accept appropriate justifications for not conducting animal tests (e.g. no pharmacologically relevant species).

The experience and technical aspects of the cited non-clinical assessor job description as worded do not exclude candidates with a specialist knowledge of non-animal, in vitro or in silico methods.

Assay validation is part of the development of any test and is therefore the responsibility of the person who is developing and conducting the assay. Companies are able to discuss the appropriateness of any developed assay and how they intend to use the data with the MHRA at any point in development through our Innovation Office or Scientific Advice services. If data from such assays are submitted in support of a Clinical trial or marketing authorisation application, the assessor will take a decision on the acceptability of the data and how this is presented in Section 5.3 of the Summary of Product Characteristics.

Assessors do have access to additional advice if required through the Commission on Human Medicines (About us - Commission on Human Medicines - GOV.UK (www.gov.uk) and can seek scientific advice on appropriate non-animal assays from the laboratory-based scientists in the Science, Research and Innovation Group of the Agency.

The MHRA advises companies against the use of animals in development of biosimilar medicines (see https://www.gov.uk/government/publications/guidance-on-the-licensing-of-biosimilar-products) . This states 'No in vivo studies from animals are requested'. The physicochemical and biological methods applied suffice to obviate any in vivo use of animals in the development of these products. This is an example of where MHRA has published information to avoid animal use, in this case, in respect of this class of product.

Further information on animal use in medicines and medical devices regulation can be found on our website at https://www.gov.uk/government/publications/animal-use-in-medicines-and-medical-devices-regulation/animal-use-in-medicines-and-medical-devices-regulationIt states that whilst the safety evaluation of new medicines and medical devices includes some data generated from animal studies, the MHRA Regulatory Centre does not conduct or sponsor any studies in animals.

MHRA Toxicologists assess non-clinical data submitted in support of applications for product licenses, or clinical trials to support their safe use in humans. They are fully aware of their responsibilities under the Animals (Scientific Procedures) Act of 1986

and Directive 2010/63/EU on the protection of animals used for scientific purposes, and regularly advise applicants on adherence to the 3Rs principles.

The MHRA fully supports the National Centre for the 3Rs (NC3Rs) and the EU's Joint Committee for Medicinal Products for Veterinary Use/Committee for Medicinal Products for Human Use Working Group on the Application of the 3Rs in Regulatory Testing of Medicinal Products (J3RsWG) in their work regarding application of the 3Rs principles.

Agency staff play an active role in projects to support adoption and adherence to the 3Rs principles in medicines regulation worldwide.

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

MHRA Customer Experience Centre
Communications and engagement team
Medicines and Healthcare products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

Telephone 020 3080 6000