FOI 23/482

Dear

We are writing in response to your request which was made on 27 April 2023. We apologise for the delay in responding to you.

> *"I am requesting a statement and update upon the continuing use of obsolete tests here in the UK. In order for any tests to be carried out on animals, all institutions are bound by law to submit a project licence. The requirements for regulatory testing is set by yourselves. Ergo you will be fully aware of what the tests are that are going to be used.*
>
> *I specifically would like to know about the Abnormal Toxicity Test and why the MHRA is allowing this obsolete and deleted test to continue to be performed here in the UK."*

As we confirmed in our internal review decision of 1 October 2023, your request asked for views and explanations rather than recorded information that we would already hold. As such, this means that it is not a valid request for recorded information under the FOI.

Under our section 16 duty to assist, we are providing some explanation in response to your questions, and we have set our explanations out in two parts below.

The MHRA position on the Abnormal Toxicity Test (ATT)

- On 08 December 2017, the European Directorate for the Quality of Medicines and Healthcare (EDQM) announced that it was removing the ATT from the European Pharmacopoeia (a process known as suppression). The EDQM is an institution of the Council of Europe, of which the United Kingdom is a member, and its decisions are legally binding on member states. The British Pharmacopoeia (BP) which is part of the MHRA and supports the UK Delegation to the EDQM, endorsed this decision. The Pharmacopoeia is a set of internationally recognised standard tests that meet the high quality required for medical products testing.

- On 18 October 2018, the European Medicines Agency (EMA), of which the MHRA was a member, released a reflection paper on 3Rs opportunities. A component of this paper related to the ATT. The EMA adopted the EDQM decision to delete the ATT. As such this test was/is not recognised as valid for any regulatory submission of medicinal products with effect from 01 January 2019.

- The British Pharmacopoeia is a set of internationally recognised standard tests that meet the high quality required for medical products testing.

Whilst the MHRA left the EMA as a result of the EU Exit, the Agency has not changed its stance on this test. Indeed, the MHRA continues to work with companies to develop animal alternatives to other biological tests and highlights such opportunities when assessing dossiers.

The UK remains part of the Council of Europe and the BP remains legally bound to the decisions of the EDQM. We also note that the World Health Organisation supported the deletion of the test in 2019.

The MHRA remit with respect to ensuring public and patient safety

The role of the MHRA is set out in the legislation of the UK. Two key pieces of this legislation are the Human Medicines Regulations 2012 and the Medicines and Medical Devices Act 2021. These can be found at Legislation.gov.uk

To support its function and ensure patient safety, the Agency publishes and updates Guidance for industry and supporting organisations such as contract research and contract testing sites (CROs, CTOs).

The MHRA will inspect sites that carry out laboratory testing in support of medicinal products that make claims of compliance with Good Manufacturing Practice. [Bearing in mind the international customer base of some organisations], it is outside of the legal remit of the MHRA to instruct an organisation on what tests it can and cannot offer.

The Home Office operates the Animals in Science Regulatory Unit which issues guidance to UK laboratories under the Animals (Scientific Procedures Act) 1986.

We hope this explanation is useful for you.

Kind Regards

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