FOI 23/348 – regulatory changes following Brexit

MHRA RESPONSE
20 June 2023

Dear

Thank you for your FOI request dated 15 May. I apologise for the delay in reply.

You asked for the following information:

1. Has your regulatory body been contacted by the Government with a request for suggestions for post-Brexit regulatory changes?
2. If you have responded to request how many regulatory changes have you proposed.
3. What are those regulatory changes that you have suggested.
4. The number of regulations that relate to your regulatory body which have already been amended or repealed due to Brexit.
5. The titles of these regulations that relate to your regulatory body which have been amended or repealed as a result of Brexit.
6. The number of regulations that relate to your regulatory body which are in anyway under review as a result of Brexit.
7. The titles of these regulations which are under review as a result of Brexit.

I can confirm we do hold some of the information you requested. However, in relation to questions 1-3, the MHRA is an executive agency of the Department of Health and is therefore part of central government. In order to determine if we do hold any relevant information, could you reframe question 1 to be more specific about which part of Government you have in mind?

With regard to your remaining questions, we have interpreted these to refer to sets of regulations. Therefore, we have amended two pieces of legislation due to Brexit. There are the Human Medicines Regulations 2012 (S.I.2012/1916) and the Medical Devices Regulations 2002 (S.I. 2002/618). There are currently three sets of regulation under review – the Human Medicines Regulations 2012, Medical Devices Regulations 2002 and the Medicines for Human Use (Clinical Trials) Regulations 2004 (S.I. 2014/1031).

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

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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