



Medicines & Healthcare products
Regulatory Agency



Mark Roberts
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www.gov.uk/mhra

30th July 2021

Dear Mr Roberts,

Our Ref: FOI 21/760

Thank you for your email dated 1st July 2021, where you asked:

“please provide all records relating to investigations into fatal outcomes of a 'serious suspected adverse reaction' over the past two years. This should include, but not be limited to, internal correspondences and minutes of meetings”

I can confirm that the MHRA collects reports of suspected adverse reactions to medicines and vaccines via the Yellow Card Scheme. Section 12 of the FOI Act specifies that a public authority may refuse requests where the cost of dealing with them would exceed the appropriate limit, which for central government is set at £600. This represents the estimated cost of one person spending 24 working hours in determining whether the department holds the information, locating, retrieving and extracting the information. We consider that extracting the information that you have requested will take longer than 24 working hours to complete.

As your request has been refused under Section 12 of the FOI Act, we cannot answer any part of it however we will be happy to provide a response to any refined request you send in the future.

I hope the information provided is helpful, but 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
Vigilance and Risk Management of Medicines Division

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If you have a query about this email, please contact us. If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the Agency who has not previously been involved in your request. If you wish to pursue that option please write to the Communications Directorate, Medicines and Healthcare products Regulatory Agency, (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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

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