

FOI 23/252 - Pharmacovigilance Inspections

REQUEST

5 April 2023

Please could you provide the following data in relation to Pharmacovigilance Inspections of Marketing Authorisation Holders:

- Number of inspection findings related to Patient Support Programs
- Breakdown by year since 2011, including grading of finding (Critical, Major, Minor)

MHRA RESPONSE

21 April 2023

Dear

Thank you for your email.

I can confirm that the MHRA does hold some of the information that you have requested. However, we have also determined that the information is exempt under Section 12 of the Freedom of Information Act and we cannot process your request any further. We are unable to fulfil the original request for the specified timeframe as this would require us to manually review 139 inspection reports to retrieve the requested information.

Section 12 of the Act allows public authorities to 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.

If you wish to refine and resubmit your request, we are able to provide the data on inspection findings concerning patient support programmes from April 2012 onwards.

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

MHRA Customer Experience Centre

Communications and engagement team
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