

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 6 June 2023

Public Authority: Medicines & Healthcare Products Regulatory Agency (Executive Agency of the Department for Health and Social Care)

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Decision (including any steps ordered)

1. The complainant has requested information about “yellow card” reporting on Covid-19 vaccinations. The above public authority (“the public authority”) relied on section 12 of FOIA (cost of compliance) to refuse the request.
2. The Commissioner’s decision is that the public authority has failed to demonstrate that section 12 of FOIA is engaged and consequently is not entitled to rely on this exemption to refuse the request.
3. The Commissioner requires the public authority to take the following steps to ensure compliance with the legislation.
 - Issue a fresh response, to the request, that does not rely on either section 12 or section 14 of FOIA
4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. On 10 February 2022, the complainant wrote to the public authority and requested information in the following terms:

"The MHRA have encouraged the public and medical fraternity to use the Yellow Card Reporting Scheme as a method to monitor adverse reactions to covid-19 vaccines. There have been many reports to date of serious adverse reactions including death following injection of the covid19 vaccines. The MHRA explains:

"Many suspected ADRs reported on a Yellow Card do not have any relation to the vaccine or medicine and it is often coincidental that symptoms occurred around the same time as vaccination."

1. Please can the MHRA provide a quantitative report showing evidence that it has formally investigated these occurrences and the conclusions reached?

"The MHRA state that where possible deaths occurring within 28 days of someone having the vaccine are investigated.

2. Please can the MHRA provide a report showing evidence of such investigations (with patient anonymity of course) and the conclusions reached?
3. Please can the MHRA provide any report(s) of investigations conducted to ascertain the reasons for any adverse reactions (sever [sic] or otherwise) from covid-19 vaccines as reported through the Yellow Card Scheme?

"In light of what must be very factors of great concern to anyone submitting to this vaccine, one assumes that the continued use of the vaccine must be based on the conclusion of a verifiable risk assessment. Could you therefore please provide me with the full basis of evidence, together with all supporting documentation and data, showing that the relevant risk factors fall within the margins of safety to justify continued encouragement to undertake vaccination."

6. The public authority originally refused the request as vexatious. The complainant referred the matter to the Commissioner who determined

that the request was not vexatious and ordered a fresh response to be provided.¹

7. The public authority issued its fresh response on 20 January 2023. It now relied on section 12 of FOIA to refuse the request as it said that the cost of complying would exceed the appropriate limit. It is this response that is the subject of this decision notice.
8. The complainant sought an internal review on the same day. Despite acknowledging the request for an internal review and agreeing to carry one out, the public authority had failed to do so at the date of this notice.

Reasons for decision

9. Section 12 of FOIA allows a public authority to refuse a request for information where it estimates that the cost of complying would exceed a certain amount. In the public authority's case, that figure is £600 – or 24 hours of staff time.
10. The public authority did not produce an estimate of the cost of complying with the request when it issued its refusal notice in January 2023 – it merely stated that complying with the request would exceed the £600 limit. As it failed to carry out an internal review, it has not provided any more detail.
11. The Commissioner wrote to the public authority on 5 May 2023 asking it to set out details of its estimate, the tasks that would be required in order to comply and any sampling exercise that had been carried out. He asked for a response by 22 May 2023. He also made clear that it was the public authority's responsibility to demonstrate to him that the exemption was engaged and that, if it failed to provide adequate submissions, he would issue a decision notice finding that the exemption was not engaged. On 22 May, the public authority asked for an extension of time until 30 May 2023 – to which the Commissioner agreed.
12. When no response had been received by the public authority's chosen deadline, the Commissioner sent further chasing correspondence on 1

¹ <https://ico.org.uk/media/action-weve-taken/decision-notices/2022/4023419/ic-161306-n4v8.pdf>

June 2023, making it clear that, if no submission was received by the end of the week, he would simply go straight to a decision notice.

13. At the date of this notice, no submission has been received from the public authority.
14. Given that the public authority has failed to produce an estimate of the cost of compliance and has failed to demonstrate why the cost would exceed the appropriate limit, the Commissioner considers that it would be unfair to the complainant to delay his decision further. He therefore finds that the public authority is not entitled to rely on section 12 of FOIA and must therefore issue a fresh response to the request that does not rely on this exemption.
15. Given that the Commissioner has already decided that section 14 does not apply to this request, it follows that the public authority may not revert back to this exemption either.

Right of appeal

16. Either party has the right to appeal against this decision notice to the First-tier Tribunal (Information Rights). Information about the appeals process may be obtained from:

First-tier Tribunal (Information Rights)
GRC & GRP Tribunals,
PO Box 9300,
LEICESTER,
LE1 8DJ

Tel: 0203 936 8963

Fax: 0870 739 5836

Email: grc@justice.gov.uk

Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

17. If you wish to appeal against a decision notice, you can obtain information on how to appeal along with the relevant forms from the Information Tribunal website.
18. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Signed

Roger Cawthorne
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF