

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 18 May 2023

Public Authority: Medicines and Healthcare products Regulatory Agency

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Decision (including any steps ordered)

1. The complainant requested information relating to Covid-19 vaccinations. By the date of this notice the Medicines and Healthcare products Regulatory Agency (MHRA) had not issued a substantive response to this request.
2. The Commissioner's decision is that MHRA has breached section 10(1) of FOIA in that it failed to provide a valid response to the request within the statutory time frame of 20 working days.
3. The Commissioner requires MHRA to take the following step to ensure compliance with the legislation.
 - MHRA must provide a substantive response to the request in accordance with its obligations under FOIA.
4. MHRA must take this step 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 FOIA and may be dealt with as a contempt of court.

Request and response

5. On 31 October 2022, the complainant wrote to MHRA and requested information in the following terms:

“Under the Freedom of Information Act, we therefore now request that you make available the following:

1) The specific criteria that you have set which will trigger a formal epidemiological study, in the context of COVID-19 vaccine safety monitoring.

2) Any and all documents, emails, or minutes of meetings referring to rapid cycle analysis in the context of COVID-19 safety monitoring.

3) Any and all documents, emails, or minutes of meetings referring to targeted active monitoring in the context of COVID-19 safety.

4) Any and all documents, emails, or minutes of meetings that you relied upon to decide how many of these fatal outcomes were caused by a COVID-19 vaccine.

5) The criteria that you have set, regarding the number of reported COVID-19 vaccine-associated deaths to the Yellow Card system, that would prompt you to call for a halt of the COVID-19 vaccination program.”

6. MHRA acknowledged the request on 31 January 2023, apologising for the substantial delay in responding. Despite repeated attempts by the complainant to elicit a response from MHRA, no such substantive response has been issued.

Reasons for decision

7. Section 1(1) of FOIA states that:

“Any person making a request for information to a public authority is entitled –

(a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and

(b) if that is the case, to have that information communicated to him.”

8. Section 10(1) of FOIA states that a public authority must respond to a request promptly and "not later than the twentieth working day following the date of receipt".
9. On 17 April 2023 the Commissioner wrote to MHRA, reminding it of its responsibilities and asking it to provide a substantive response to the complainant's request within 10 working days.
10. Despite this intervention MHRA has failed to respond to the complainant.
11. From the evidence provided to the Commissioner in this case, it is clear that MHRA did not deal with the request for information in accordance with FOIA. The Commissioner finds that MHRA has breached section 10(1) by failing to respond to the request within 20 working days and it is now required to respond to the request in accordance with FOIA.

Right of appeal

12. 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

13. 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.
14. 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

Michael Lea
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Water Lane
Wilmslow
Cheshire
SK9 5AF