

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 4 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 about actions taken regarding covid vaccines. By the date of this notice the Medicines and Healthcare products Regulatory Agency ("the MHRA") had not issued a substantive response to this request.
2. The Commissioner's decision is that the 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 the MHRA to take the following step to ensure compliance with the legislation.
 - the MHRA must provide a substantive response to the request in accordance with its obligations under FOIA.
4. The 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 7 March 2023, the complainant wrote to the MHRA and requested information in the following terms:

"In the Coronavirus vaccine - summary of Yellow Card reporting, you state that "we work with our international counterparts to gather information on the safety of vaccines in other countries" and also "when a safety issue is confirmed the MHRA will act promptly to inform patients and healthcare professionals and take appropriate steps to mitigate any identified risk".

Therefore, under the 'Freedom of Information Act 2000', I request disclosure of the following:

- 1) Details of the prompt actions taken by the MHRA following the Danish health authority suspending

the Astra Zeneca vaccine's use for all age groups on 11 March 2021 (pending a detailed analysis) beyond the advice given by [REDACTED] on 18 March 2021. For example, the Danish Ministry sent a letter to every person who had received AZ in the previous 14 days, telling them what symptoms to look out for and when to contact their doctor

- 2) How many doses of the AstraZeneca vaccine were given to patients, between the period of 11 March 2021 to 7 May 2021.

- 3) Any internal minutes where the Danish development or cerebral venous sinus thrombosis was discussed, including but not limited to your regular COVID-19 Vaccine Signal Meetings.

- 4) Why the Danish health authority's safety concern was not on the agenda of the next MHRA board meeting, held on 16 March 2021."

6. The MHRA acknowledged the request on 8 March 2023. To date, a substantive response has not 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 13 April 2023 the Commissioner wrote to the 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 the MHRA has failed to respond to the complainant.
11. From the evidence provided to the Commissioner in this case, it is clear that the MHRA did not deal with the request for information in accordance with FOIA. The Commissioner finds that the 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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