

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 9 November 2022

Public Authority: Medicines and Healthcare Products Regulatory Agency

Address: 10 South Colonnade
London
E14 4PU

Decision (including any steps ordered)

1. The complainant requested information in relation to delegations to the MHRA on who can authorise medicine for public use. 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 31 July 2022, the complainant wrote to the MHRA and requested information in the following terms:

"1. The Human Medicines Regulations define the Licensing Authority as the Secretary of State for Health & Social Care. Please can you send me the MHRA document describing the flow of delegation from the SofS to posts/people in MHRA who can authorise medicines for public use.

2. Regulation 174 of the Human Medicines Regulations allows the temporary authorisation of medicines.

Please can you send me a copy of the instruction to MHRA that Regulation 174 applied to the Covid vaccines.

Please can you tell me which post/person in MHRA signed the temporary authorisations for public use of the Covid vaccines.

Please can you send me copies of the MHRA's one year reviews of the temporary authorisation for each of the Covid vaccines."

6. The MHRA on 31 July 2022 acknowledged the request. To date, a substantive response has not been issued.

Scope of the case

7. The complainant contacted the Commissioner on 29 September 2022 to complain about the MHRA's failure to respond to their request.
8. The Commissioner has considered whether the MHRA has complied with its obligations in relation to the time for compliance at section 10(1) of FOIA.

Reasons for decision

9. 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.”

10. 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".
11. On 7 October 2022 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.
12. Despite this intervention the MHRA has failed to respond to the complainant.
13. 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

14. 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

15. 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.
16. 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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