

## **Freedom of Information Act 2000 (FOIA)**

### **Decision notice**

**Date:** 31 March 2023

**Public Authority:** Medicines and Healthcare Products Regulatory Agency

**Address:** 10 South Colonnade  
Canary Wharf  
London  
E14 4PU

#### **Decision (including any steps ordered)**

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1. The complainant requested information about a report and a presentation carried out by the Medicines and Healthcare Products Regulatory Agency ("the MHRA") to the Commission on Human Medicines Pharmacovigilance Expert Advisory Group in June 2022. By the date of this notice, 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 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**

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5. On 30 January 2022, the complainant wrote to the MHRA and requested information in the following terms:

"I am very concerned about the effect of the unprecedented number of Yellow Card reports associated with the Covid vaccines on the statistical methods you use in Pharmacovigilance.

In June 2022 MHRA gave the Commission on Human Medicines Pharmacovigilance Expert Advisory Group :

a) a presentation on how MHRA conducts disproportionality analysis as part of your signal detection process, and

b) the report of an investigation into the impact of the large proportion of Covid vaccine reports in the Yellow Card database on disproportionality analysis and signal detection.

I would be grateful if you could send me a copy of a) and b) above."

6. The MHRA acknowledged the request on 6 January 2023. To date, a substantive response has not been issued.

## **Reasons for decision**

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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 23 March 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 5 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

Reference: IC-221968-G8C2



working days and it is now required to respond to the request in accordance with FOIA.

## Right of appeal

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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](mailto:grc@justice.gov.uk)

Website: [www.justice.gov.uk/tribunals/general-regulatory-chamber](http://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**  
**Team Manager**  
**Information Commissioner's Office**  
**Wycliffe House**  
**Water Lane**  
**Wilmslow**  
**Cheshire**  
**SK9 5AF**