

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 13 December 2022

Public Authority: Medicines and Healthcare products Regulatory Agency(MHRA)

Address: 10 South Colonnade
Canary Wharf
London E14 4 PU

Decision

1. The Commissioner's decision is that MHRA is entitled to withhold information associated with its Yellow Card Scheme under sections 40(2) and 41(1) of FOIA which concern personal data and information provided in confidence respectively. MHRA's response to the request did not comply with section 10(1) or 17(1) of FOIA, which concern timeliness. The Commissioner does not require MHRA to take any steps.

Request and response

2. The complainant made the following information request to MHRA on 17 August 2022:

"Please provide the following files:

- All versions of the document referred to as the "PV Strategy Document" or "Refined PV strategy document" in the December 2021 and June 2022 versions of "Monitoring and signal detection activities for ADR reports concerning the COVID-19 vaccine"

- The "AESI Line Listing.xlsx" file in this sub-folder:
"https://mhra.sharepoint.com/.../Covid-19 vigilance/COVID-19 Vaccine".

- All files in the sub-folder: [https://mhra.sharepoint.com/.../Covid-19 vigilance/COVID-19 Vaccine/COVID-19 mRNA BioNTech Case Outputs](https://mhra.sharepoint.com/.../Covid-19%20vigilance/COVID-19%20Vaccine/COVID-19%20mRNA%20BioNTech%20Case%20Outputs)”

3. MHRA’s final position was to disclose some relevant information – a paper called “Refining the MHRA COVID-19 Vaccine Safety Surveillance Strategy in preparation for potential extensions to the deployment programme”. MHRA refused to disclose the remainder of the requested information under section 40(2) and section 41(1) of FOIA.

Reasons for decision

4. This reasoning covers MHRA’s refusal of the request under sections 40(2) and 41(1) of FOIA, and the timeliness of its response.
5. In its internal review response MHRA advised that, as outlined in its Privacy Policy, MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless it is required or permitted to do so by law. The Policy also states that MHRA may receive requests for Yellow Card report data under the Freedom of Information Act. MHRA explained that while it is legally obliged to provide some of the requested information, it only provides high-level summary information with all person-identifiable data excluded.
6. MHRA said that the data within the requested files is listed case by case, containing all information received from the original reporter which includes person-identifiable information. MHRA noted that the complainant has asked whether personal information can be redacted from these documents in order for it to deem these releasable.
7. MHRA advised that, unfortunately, due to the way this information is held, even if the personal identifiers were redacted, the cumulative information for each individual report could identify the patient or reporter. MHRA maintained that providing the information in the second part of the request, could lead to an individual being identified, and therefore is exempt under section 40 and 41. Those about whom Yellow Card reports have been submitted have not consented to their personal data being supplied to third parties other than as outlined in the Privacy Policy. Additionally, MHRA said, it would contravene data protection principles.
8. The Commissioner has previously made a decision on a request submitted to MHRA for information associated with its Yellow Card Scheme: [IC-111457-W7C5](#). He decided that the information was exempt from disclosure under section 40(2) and section 41(1).

9. The reasoning in that decision applies equally to the current decision, such that the Commissioner does not intend to reproduce the reasoning but directs the complainant to that notice.
10. As in that earlier case, the Commissioner is satisfied that the information the complainant has requested is exempt from disclosure under the two exemptions MHRA has cited. Neither section 40(2) nor section 41(1) are subject to the public interest test under sections 2(1)(b) and 2(2)(b) of FOIA, as such, but public interest considerations are included in the Commissioner's reasoning in IC-111457-W7C5.
11. Under section 10(1) a public authority must communicate relevant information it holds within 20 working days of a request. Within the same timescale under section 17(1) of FOIA the authority must issue a refusal notice in respect of any exempt information.
12. In this case, MHRA did not disclose the paper until its internal review on 27 October 2022 and had not issued its refusal until 28 September 2022. MHRA therefore did not comply with sections 10 and 17 of FOIA.

Right of appeal

13. 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: 0300 1234504
Fax: 0870 739 5836
Email: grc@justice.gov.uk
Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

14. 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.
15. 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

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