Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **17 February 2022**

Public Authority: **Medicines & Healthcare products Regulatory Agency (Executive Agency of the Department for Health and Social Care)**

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

Decision (including any steps ordered)

1. The complainant requested information from the Medicines & Healthcare products Regulatory Agency ("MHRA") about suspected adverse cardiac reactions to Covid-19 vaccines.

2. The Commissioner's decision is that the MHRA were entitled to refuse to comply with the request under section 12(1) of FOIA (cost of compliance), and that it has complied with its obligations under section 16(1) of FOIA to provide adequate advice and assistance to the complainant.

3. The Commissioner does not require the public authority to take any further steps.

Request and response

4. On 17 May 2021, the complainant wrote to the MHRA and requested information in the following terms:

> "Please can you confirm whether the MHRA holds any information - including, but not limited to, e-mails, text messages (including SMS messages, iMessage messages, WhatsApp messages and Telegram messages), messages on internal chat systems (such as Slack and Microsoft Teams), and documents (including unfinished/unpublished

versions of documents) - which in any way relates to the following suspected adverse reactions to COVID-19 vaccines:

- Myocarditis

- Pericarditis

- Other cardiac disorders

If any such information exists, please can you provide it to me, in each case ensuring it is clear which COVID-19 vaccine or vaccines is/are involved (except where this is unknown)."

5. The MHRA responded on 15 June 2021, citing section 12(1) FOIA to refuse the disclosure of the requested information and the MHRA went on to uphold their initial response at internal review on 8 July 2021.

Scope of the case

6. The complainant contacted the Commissioner on 15 July 2021 to complain about the way their request for information had been handled.

7. The Commissioner considers the scope of this case is to determine if the public authority has correctly cited section 12(1) of FOIA in response to the request.

Reasons for decision

Section 12 – cost of compliance exceeds the appropriate limit

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

"(1) 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."

9. Section 12(1) of FOIA states that:

> "Section 1(1) does not oblige a public authority to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate limit."

10. The Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 ("the Regulations") sets the appropriate limit at £600 for the public authority in question. Under the Regulations, a public authority may charge a maximum of £25 per hour for work undertaken to comply with a request. This equates to 24 hours work in accordance with the appropriate limit set out above.

11. A public authority is only required to provide a reasonable estimate, rather than a precise calculation, of the cost of complying with the request, and in putting together its estimate it can take the following processes into consideration:

    - determining whether the information is held
    - locating the information, or a document containing it;
    - retrieving the information, or a document containing it; and
    - extracting the information from a document containing it.

12. A public authority does not have to make a precise calculation of the costs of complying with a request; instead, only an estimate is required. However, it must be a reasonable estimate. In accordance with the First-Tier Tribunal decision in the case of Randall v IC & Medicines and Healthcare Products Regulatory Agency EA/20017/0004[1], the Commissioner considers that any estimate must be *"sensible, realistic and supported by cogent evidence".*

13. Where a public authority claims that section 12(1) of FOIA is engaged it should, where reasonable, provide advice and assistance to help the applicant refine the request so that it can be dealt with under the appropriate limit, in line with section 16(1) of FOIA.

The MHRA's position

14. The MHRA informed the Commissioner that when the request was initially received, work was undertaken to confirm if the information was

[1] https://informationrights.decisions.tribunals.gov.uk/DBFiles/Decision/i136/Randall.pdf

held. It explained that to provide the information requested it would require locating, retrieving, extracting, and collating information and data from specific business areas and information sources. Due to the breadth and nature of the request, they estimated that meeting the request could not be done within the appropriate limit set out by FOIA.

15. The MHRA further explained that it became apparent that the work involved to obtain the initial information would exceed the cost limit:

> "We have broken the request down into the four areas cited and, as a scoping exercise, have used the Yellow Card reports that would come within the remit of this request."

16. The MHRA went on to explain to the Commissioner:

> 'Within the weekly summary of Yellow Card reporting containing data up to and including 15 May 2021, over 235,000 Yellow Cards had been reported for the COVID-19 Vaccines.'

17. And went on to further refine this:

> "As a starting point, a search would have to be conducted on each FTE's e-mails, text messages and messages on internal chat systems for each of these Yellow Card reference numbers or hyperlinks. It is estimated that one individual could search for 180 Yellow Cards within one platform (e.g. Microsoft Outlook) in an hour, therefore it would take each individual approximately 48 hours to complete this search on one platform.
>
> Furthermore, each of these Yellow Cards may have been discussed at the daily COVID-19 meetings we held to discuss adverse reaction reports: this means that further searches would need to be conducted of the minutes of each of these, as well as the relevant Teams channels.
>
> Further searches would also have to be conducted for each FTE regarding the assessment of these reports, our discussions on these with public health partners and other regulatory authorities, and correspondence with healthcare professionals and members of the public about the reports. Separate searches would also need to be conducted to cover our work with various Marketing Authorisation Holders (MAHs) (the companies responsible for each product)."

18. They also advised within the internal review that:

> "When reviewing your original FOI request, it was noted that it was very detailed on what information you requested including that this

should not be limited to those listed. If you are able to refine your request to clarify specifically the information you are seeking as a separate FOI request the MHRA will consider that further.

In order to further assist you with your original questions about suspected cardiac ADRs potentially associated with COVID-19 vaccines, please note that our website sets out the current adverse events reported to MHRA through the Yellow Card Scheme which also includes myocarditis and pericarditis. The current published data can be accessed here: (link provided)

Our webpage also provides regular public updates in relation to the on-going monitoring of the risk:benefit balance of these medicines which includes details of the Public Assessment Reports and the product information which is approved for both healthcare professionals and patients. These pages also include announcements through press releases of the latest advice to healthcare professionals and patients."

19. From the MHRA's submissions and the initial investigatory work undertaken; it was evidenced that to comply with the request in full would exceed the appropriate limit.

The Commissioner's conclusion

20. Paragraph 6.6 of the Freedom of Information (FOI) Code of Practice states:

"Public authorities do not have to search for information in scope of a request until the cost limit is reached, even if the applicant requests that they do so. If responding to one part of a request would exceed the cost limit, public authorities do not have to provide a response to any other parts of the request.[2]"

21. The Commissioner's guidance states that whilst a public authority may search up to or even beyond the appropriate limit of its own volition, there is no requirement for a public authority to do so. For more information, see paragraph 28 onwards of the Commissioner's guidance on costs of compliance exceeds appropriate limit.[3]

[2] CoP FOI Code of Practice - Minor Amendments 20180926 .pdf (publishing.service.gov.uk)

[3] https://ico.org.uk/media/for-organisations/documents/1199/costs_of_compliance_exceeds_appropriate_limit.pdf

22. During the investigation, the MHRA provided the Commissioner with an explanation of what it would need to do to obtain the requested information. The Commissioner accepts that the MHRA's estimates are reasonable and that it would exceed the appropriate limit to obtain the information.

23. The Commissioner acknowledges the complainants view that disclosure of the information is in the public interest and why the complainant would want this information, however, section 12 of FOIA is not subject to a public interest test.

24. Therefore, the Commissioner considers that the MHRA estimated reasonably that the request could not be answered within the cost limit, and as such, the MHRA are entitled to rely on section 12(1) of FOIA to refuse the request.

Section 16(1) – duty to provide advice and assistance

25. Section 16 of FOIA states:

> *"(1) It shall be the duty of a public authority to provide advice and assistance, so far as would be reasonable to expect the authority to do so, to persons to propose to make, or have made, requests for information to it.*
>
> *(2) Any public authority which, in relation to the provision of advice or assistance in any case, conforms with the code of practice under section 45 is to be taken to comply with the duty imposed by subsection (1) in relation to that case."*

26. Where a public authority refuses a request under section 12(1) of FOIA, section 16(1) creates an obligation to provide advice and assistance on how the scope of the request could be refined or reduced to avoid exceeding the appropriate limit.

27. In this case, in their internal review, the MHRA suggested refining the request and advised the complainant of the information that was available online and included links.

28. The Commissioner has considered the advice and assistance provided to the complainant by the MHRA, and paragraph 6.9 of FOIA Code of Practice advises that helping an applicant narrow the scope of their request may include suggesting that the subject or timespan of the request is narrowed.

29. The Commissioner considers that the advice and assistance the MHRA offered the complainant was adequate. The Commissioner is therefore satisfied that the MHRA have complied with its obligations under section 16(1) of FOIA in its handling of this request.

Right of appeal

30. 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

31. 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.

32. 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 .....

Phillip Angell
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