Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 12 April 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 adverse reactions to Covid-19 vaccines, reported through the yellow card reporting system.

2. The MHRA has cited section 12(1) of FOIA (cost of compliance) to refuse the request for information. The Commissioner's decision is that the MHRA were entitled to refuse to comply with the request under section 12(1) of FOIA, 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 8 June 2021, the complainant wrote to the MHRA and requested information in the following terms:

> "Please provide an anonymised version of the database of adverse reactions to the various Covid vaccines reported through the yellow card reporting system. Please include ALL data collected for each report, such as the age of the individual, sex of the individual, the identity of the vaccine, whether the reaction is to the first or second vaccination, and how long after the vaccination the reaction occurred, etc." Please share the data in an easily accessible format, appropriate to the size of the file, and using commonly available spreadsheet software."

5. The MHRA responded on 6 July 2021, citing section 22(1) of FOIA to refuse the disclosure of the requested information and the MHRA went on to uphold their initial response at internal review on 16 July 2021, and cited section 12(1) applied to the specific request for redacted reports to be prepared.

6. As a result of the Commissioners investigation and after correspondence with MHRA regarding their responses to the requestor, the MHRA revoked their reliance on section 22(1) stating "the Agency has reconsidered its position here, and on further reflection, it would not be appropriate to rely on section 22 as the entirety of the request could not be covered under this exemption". Subsequently MHRA citied section 12(1) to refuse the request.

Scope of the case

7. The complainant contacted the Commissioner on 20 July 2021 to complain about the way their request for information had been handled.

8. 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

9. 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."

10. 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."

11. 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.

12. 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.

13. 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".*

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

14. 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

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

16. 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 areas cited and, as a scoping exercise, have used the Yellow Card reports that would come within the remit of this request."

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

> "Within the weekly summary of Yellow Card reporting containing data up to and including 9 June 2021, over 275,000 Yellow Cards had been reported for the COVID-19 Vaccines."

18. And went on to further refine this:

> "Due to the sheer volume of relevant Yellow Cards and functionality of our data extraction system, these would need to be split into more manageable volumes to produce the desired output. Approximately 1,000 Yellow Cards could have the relevant data fields extracted from them at once, meaning the output would need to be ran 275 times. We estimate that the time taken to validate, retrieve and extract one output, without considering the relevant review processes, would take approximately 90 minutes. A further 30 minutes would be needed between each run to check all relevant Yellow Cards had been included. Therefore, for this stage of the process alone to be completed for over 275,000 Yellow Cards this would take over 550 hours."

1) MHRA explained that a query would need to be built in their 'Signal Management' (SM) software. The query would include all relevant criteria, this takes approximately 10 minutes and to execute approximately 25 minutes.

2) A second query would need to be built in separate alternative software as a cross check to ensure SM retrieved all relevant cases. Again, this step takes approximately 10 minutes and a further 45 minutes to execute.

3) Both outputs would need to be compared to ensure the results are the same form each programme, and that there are no Adverse Drug Reactions (ADR) reports missing. If outputs differ, further work would be required to understand any discrepancies.

19. The MHRA continued that whilst the queries are processing, the assessor is unable to complete further work using either programme, also steps one and two cannot be completed at the same time due to software limitations. Further considerations need to be taken on the best way to present the data in a suitable format, a further report would need to be run which would take an additional 30 minutes.

20. The MHRA advised that this process is currently the quickest method to run automatically. The MHRA also said it is committed to implement new systems for data provision across medical products including vaccines, which will enable MHRA to provide an improved format for publishing data. This data should be available from the end of 2022.

21. The MHRA also advised within the internal review to the complainant that:

> "As you know from our earlier response, we have already provided to you with links to the adverse events which have been identified as a result of our Covid Vaccine Surveillance Strategy. These links are provided again for ease of reference.
>
> These reports include drug analysis prints for all vaccines currently deployed in the UK and for which we have received reports of adverse events along with the total number of adverse events reported to us. For context the estimated number of doses of each vaccine is also included.
>
> It remains our intention to seek permission to publish interactive drug analysis prints (iDAPs) for vaccines which would enable stratification of the data by a number of factors including age.
>
> On the basis of the foregoing, I conclude that the MHRA has met its obligations and has been helpful in providing answers to the questions which you have posed of us, and the information requested. As pledged earlier, my colleagues will provide a link to the iDAPs when these become available."

22. From the MHRA's submissions and the initial investigatory work undertaken; the MHRA has evidenced that to comply with the request in full would exceed the appropriate limit. For MHRA to comply with this element of the request, they would need to validate, extract, retrieve, and check all iDAPs have been included in just over five minutes for each report. The Commissioner is satisfied this would not be possible given the constraints of the current software used and system limitations.

The Commissioner's conclusion

23. 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]"

24. 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]

25. 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.

26. The Commissioner acknowledges the complainant's 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.

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[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

27. The complainant has argued that MHRA shares the requested data with Marketing Authorisation Holders (MAHs) and the World Health Organisation (WHO) and therefore is able to make this information available to them.

28. The MHRA explained that data is shared using internal information systems which share the reports automatically in an electronic format. This format is not downloadable and therefore cannot be shared with the complainant. The MHRA are currently working on a solution which will enable them to publish data in an improved format, which they state should be available by the end of 2022.

29. 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

30. 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."*

31. 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.

32. 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.

33. 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.

34. 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

35. 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

36. 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.

37. 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 .....

Philip Angell
Group Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF