Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 20 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 suspected adverse reactions to Covid-19 vaccines. The MHRA initially advised the requester that they publish weekly Yellow Card data including adverse reactions and provided a link to their website. They stated that an interactive format of all suspected reactions to the Covid-19 vaccinations was intended for future publication, but due to current system constraints, they were unable to provide it in the requested format at this time.

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 section 22(1) of FOIA (future publication), and that it has complied with its obligations under section 16(1) of FOIA to provide adequate advice and assistance to the complainant. However, MHRA breached section 17(1) as it did not initially identify the exemptions being relied upon to withhold the requested information.

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

Request and response

4. On 3 June 2021, the complainant wrote to the MHRA and requested information in the following terms:

> "I would like to know how many records you have of people claiming to have had adverse reactions to the Covid19 vaccines. I understand that you operate the yellow card scheme, and you therefore hold this information.
>
> To further clarify, I would like a tabulated collection of all the data you hold regarding reports of adverse reactions to the Covid19 vaccines. That's to say I'd like a spreadsheet containing all reports to date along with details of each report, for example the time and date of the report and the type of reaction that has been reported i.e., Allergic reaction, blood clot, death etc. A simple spreadsheet containing all of this relevant information would suffice."

5. The MHRA responded on 1 July 2021 stating that they publish yellow card information on a weekly basis which includes assessment of the data. They also stated their intention to publish interactive spreadsheets (iDAP's) at a later date.

6. On 5 July 2021 the complainant expressed their dissatisfaction with the MHRA's response and requested an internal review. At internal review on 2 August 2021, the MHRA cited section 12(1) and section 22(1) of FOIA to refuse the requested information.

Scope of the case

7. The complainant contacted the Commissioner on 4 August 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) and section 22(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 internal review request was received, work was undertaken to confirm if the information was held. It explained that to provide the information in the requested format 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 four 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 refine this:

> "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. 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. 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."

MHRA further explained that:

1) "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. They 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.

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. In his complaint to the Commissioner, the complainant has argued;

"They publish weekly reports of this so I know they hold the information. All I would like is the complete collection of data, instead of the broken down weekly reports. All I want is a spreadsheet of all the information they already hold, and publish weekly, surely they must have a database already containing all of that information."

23. The MHRA further 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 without access to the internal information systems. 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.

The Commissioner's conclusion

24. 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]"

25. 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]

26. During the Commissioners investigation, the MHRA provided the Commissioner with an explanation of what it would need to do to obtain

[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

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.

27. 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.

28. 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

29. 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."*

30. 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.

31. In this case, in their internal review, the MHRA advised the complainant of the information that was available online and included links, as well as advising of its intentions to publish further data in future which would help refine the information available online.

32. 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.

Section 22 – Information intended for future publication

33. Section 22(1) of the FOIA states that information is exempt information if:

"(a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not)

(b) the information was already held with a view to such publication at the time when the request for information was made, and

(c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in (a)."

34. Each of the three criteria must be met for the exemption to be engaged. It is also subject to a public interest test, meaning that the information must nevertheless be disclosed if the public interest in doing so is stronger than that in maintaining the exemption.

35. In its response to the complainant's request, the MHRA said that it was in the process of preparing information "We intend to publish all suspected reactions reported in association with available COVID-19 vaccines in an interactive format as iDAPs, along with our ADR summary that is published each week."

36. In its submission to the Commissioner, and in the subsequent investigation carried out by him, MHRA confirmed that it holds the requested information. Of relevance here is MHRA's 'Yellow Card' website[4]. Through this website MHRA collects and monitors information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices.

37. Interactive Drug Analysis Profiles (iDAPs) for a wide range of medicines on the Yellow Card website contain complete data for all spontaneous suspected adverse drug reactions, or side effects, which have been reported on that drug substance to the MHRA via the Yellow Card scheme, from healthcare professionals and members of the public.

38. iDAPs enable people to interact with the data so they can understand more about the types of reactions that have been reported and, at a high level, about who experienced the side effects.

39. The iDAP for each medicine featured on the Yellow Card website report against a number of factors, including those referred to in the complainant's request.

[4] Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)

40. However, medicines associated with coronavirus have their own Yellow Card reporting site[5]. At the point of the request, and currently, individuals can submit an adverse reaction report about a COVID-19 vaccine through the coronavirus Yellow Card site but are not able to access the same detailed iDAP data that is available for other medicines on the main site. However, the Coronavirus Yellow Card scheme publishes a weekly summary report of adverse reactions to approved COVID-19 vaccines[6].

41. Following correspondence with MHRA and having considered the data that MHRA currently publishes about other medicines on the Yellow Card website, the Commissioner is satisfied that the data that the complainant has requested about the COVID-19 vaccines is data that MHRA holds and intends to publish. This is because it holds the same data about other medicines.

42. MHRA notes, correctly, that section 22 of FOIA does not oblige it to commit to a specific, future publication date. However, MHRA has advised the Commissioner that it expects to publish the data in question by the end of 2022.

43. MHRA has provided the Commissioner with email exchanges covering the period 23 February 2021 to 2 March 2021. In these exchanges members of MHRA staff discuss technical and presentational issues associated with the publication of the requested data. As such, the Commissioner is satisfied that, at the time of the request on 3 June 2021, MHRA held the data with a view to publishing it at a future date.

44. The Commissioner is satisfied that the first two criteria at paragraph 33 have been met; MHRA held the requested data with a view to publishing it at some future date and the data was held with a view to such publication when the complainant submitted his request.

45. Finally, the Commissioner has considered whether it was reasonable in all the circumstances to withhold the requested data. The Commissioner's published guidance on section 22 acknowledges that there is some overlap between the factors to consider when deciding what is reasonable, and those which are relevant to the application of the public interest test. However, the Commissioner's guidance goes on

[5] Official MHRA side effect and adverse incident reporting site for coronavirus treatments and vaccines | Coronavirus (COVID-19)

[6] Coronavirus (COVID-19) vaccines adverse reactions - GOV.UK (www.gov.uk)

to suggest that when determining whether or not it is reasonable, in all the circumstances, to withhold information a public authority should consider whether or not it is sensible, in line with accepted practices, and fair to all concerned. Of relevance here, the guidance advises that an authority may also wish to give thought to whether it is the right decision to manage the availability of the information by planning and controlling its publication.

46. Regarding planning and controlling the information's publication, MHRA says in its submission that it considers that the reasons it gave to the complainant in its August 2021 response are still valid. In addition, MHRA says it will be developing a more appropriate route to publication in summer 2022 that will allow it to mitigate the risks it has identified. It will begin implementing new systems for providing data across all medical products, including vaccines. MHRA says this will enable it to produce an improved and more suitable format for publishing data in general. Specifically in this case, alongside raw data MHRA says that it intends to develop extensive communication materials to manage misuse of data, to mitigate any risks associated with misinterpretation of the data and to manage the resources associated with publishing the data. That is in addition to the continued MHRA response to the pandemic.

47. The Commissioner has taken account of MHRA's position above. The notion of 'fairness' is less of a factor in this case, but the Commissioner accepts too that withholding the information at the time of the request was sensible i.e. it was not totally illogical, and that it was in line with MHRA's accepted practices. This is because it is MHRA's practice to provide full and clear context against each medicine reported on the Yellow Card site as having generated an adverse reaction.

48. The Commissioner considers that it was reasonable in all the circumstances for MHRA to withhold the requested information at the time of the request and the internal review. Since the three criteria at paragraph 32 have been met, the Commissioner's decision is that MHRA was entitled to withhold the information the complainant has requested under section 22(1) of the FOIA. He has gone on to consider the public interest test.

Public interest test

Public interest in disclosing the information

49. The MHRA has noted in its submission that there is a potential benefit and public interest in transparency about the COVID-19 vaccine ADR data.

Public interest in maintaining the exemption

50. In its submission to the Commissioner, MHRA has said that, in considering the public interest test, it took into account how releasing data on only those vaccines used in the COVID-19 pandemic could undermine the wider Government public health campaign for widespread COVID-19. MHRA concluded it was a risk to public health and safety, and not in the public interest.

51. MHRA says that the evidence for this risk can be seen, for example, in the termination by the Japanese Government of a human papillomavirus vaccine programme following misinterpretation of published data. In that instance, unsubstantiated claims around safety have been estimated to have the potential to result in eleven thousand deaths[7].

52. It is clear, in MHRA's view, that care must be taken in preparing vaccine data for publication to mitigate catastrophic outcomes. For that reason, MHRA confirmed its stance that maintaining the exemption outweighed any potential benefit in publishing the data [at the time of the request].

Balance of the public interest

53. MHRA says that it carefully weighed the disbenefit of publishing the data without context; the potential for misinterpretation and misuse of sporadic and isolated reports; and the potential subsequent tangible harm against the potential benefit of transparency and wider public interest in publishing the information now (i.e. at the time of the request). On balance, MHRA says, it remains of the view that the public interest is best served through publishing the data in the future, with contextual narrative. At that point, by providing context to the data and clear guidance on what is being presented, the risk of misuse will be minimised.

54. The Commissioner notes that the main Yellow Card website states that when people review the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report (i.e., the 'context' information) to ensure that they do not misinterpret the data.

55. The Commissioner has noted the complainant's arguments. He fully appreciates the strong public interest there was, and is, in the COVID-19 vaccines and any adverse reactions people may have experienced after

[7] Japan's halt of regular HPV vaccine to cause thousands of cancer deaths: study | Reuters

having received one. However, given the significance of the vaccines and the sensitivities surrounding them, the Commissioner considers that there is stronger public interest in MHRA being able to publish the iDAP data for the vaccines in line with its planned timetable. This will ensure that MHRA has had the time it needs to consider the risks associated with publishing this information; how best to present the information alongside context and guidance so as to minimise the risk of the information being misinterpreted or misused. That is a complex process.

56. The Commissioner has also given weight from the information MHRA supplied in support of the application of section 12 to the initial request. The Commissioner accepts that disclosure of the information at the time of the request would have a significant impact on the MHRA's resources and would divert its staff from conducting other tasks. This would not be in the public interest.

57. Taking all the above into consideration, the Commissioner has concluded that the public interest favours maintaining the exemption. The MHRA was therefore entitled to rely on section 22(1) of FOIA to refuse the request.

Section 17

58. Section 17 FOIA states that:

(1)A public authority which, in relation to any request for information, is to any extent relying on a claim that any provision of Part II relating to the duty to confirm or deny is relevant to the request or on a claim that information is exempt information must, within the time for complying with section 1(1), give the applicant a notice which—

(a)states that fact,

(b)specifies the exemption in question, and

(c)states (if that would not otherwise be apparent) why the exemption applies.

59. In this case the MHRA did not identify which exemption they were relying upon under FOIA to refuse to disclose the requested information. MHRA did not specify it was relying upon the exemption at section 22(1) of FOIA. The MHRA therefore breached section 17(1) FOIA in its handling of the request.

Right of appeal

60. 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

61. 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.

62. 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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