Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **25 August 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. MHRA refused the request as it considered that compliance would exceed the cost limit under section 12(1) FOIA.

2. The Commissioner's decision is that MHRA has correctly cited section 12(1) FOIA in response to the request. He also finds that MHRA complied with its obligations under section 16(1) FOIA to provide 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 16 June 2021, the complainant requested information in the following terms:

"Please can you confirm whether the MHRA holds any information which 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).

For clarity, "information" refers to all recorded information held by the MHRA - including, but not limited to, e-mails and other correspondence, messages on internal chat systems (such as Slack, Google Chat/Hangouts and Microsoft Teams), and documents (such as reports, slide decks, transcripts, minutes and notes), including unfinished/unpublished versions of such.

However, if it is necessary to ensure the cost of dealing with this request does not exceed the statutory appropriate limit (but only if it is necessary), it is acceptable to constrain your searches to the electronic records of those working on the licensing of, and/or pharmacovigilance for, COVID-19 vaccines.

For the avoidance of doubt, this request is a refined version of a request considered [in a decision notice issued under ICO case reference IC-117978-K9G4[1]].

5. On 7 July 2021, MHRA responded, advising that compliance with the request would exceed the cost limit. MHRA refused the request under section 12 FOIA.

6. The complainant requested an internal review on 8 July 2021. MHRA provided an internal review response on 21 September 2021, albeit that the response was dated 9 August 2021. MHRA maintained its reliance on section 12 FOIA. It also cited section 35 FOIA (formulation of government policy) and section 27 FOIA (international relations) as applicable exemptions.

[1] https://ico.org.uk/media/action-weve-taken/decision-notices/2022/4019679/ic-117978-k9g4.pdf

Scope of the case

7. The complainant contacted the Commissioner on 24 September 2021 to complain about the way the request for information had been handled. In particular, the complainant was concerned that MHRA had incorrectly cited section 35 FOIA as an exemption and had not provided them with advice or assistance.

8. On 13 May 2022, MHRA advised the Commissioner that it wished to rely solely on section 12 FOIA in relation to the request.

9. The Commissioner therefore considers the scope of this case to be to determine if MHRA has correctly cited section 12(1) FOIA in response to the request.

10. The Commissioner has also considered whether MHRA complied with its duty to provide advice and assistance under section 16 FOIA.

Reasons for decision

Section 12 – cost of compliance exceeds the appropriate limit

11. Section 12(1) of FOIA states that a public authority is not obliged to comply with a request for information if the authority estimates that the cost of complying with the request would exceed the appropriate cost limit.

12. The appropriate limit is set in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 ('the Fees Regulations') at £600 for public authorities such as MHRA.

13. The Fees Regulations also specify that the cost of complying with a request must be calculated at the rate of £25 per hour, meaning that section 12(1) FOIA effectively imposes a time limit of 24 hours for MHRA to deal with this request.

14. Regulation 4(3) of the Fees Regulations states that a public authority can only take into account the cost it reasonably expects to incur in carrying out the following permitted activities in complying with the request:

    - 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.

15. 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), the Commissioner considers that any estimate must be "sensible, realistic and supported by cogent evidence".

16. Section 12 FOIA is not subject to a public interest test; if complying with the request would exceed the cost limit then there is no requirement under FOIA to consider the public interest.

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

Would the cost of compliance exceed the appropriate limit?

18. The Commissioner has considered whether the estimated cost of complying with the request would exceed the appropriate limit of 24 hours.

19. MHRA recognised that the request was almost identical to the previous request considered in the decision notice referred to at paragraph 4 above, although in revising the request the complainant had added the caveat:

    "..if it is necessary to ensure the cost of dealing with this request does not exceed the statutory appropriate limit (but only if it is necessary), it is acceptable to constrain your searches to the electronic records of those working on the licensing of, and/or pharmacovigilance for, COVID-19 vaccines."

20. The Commissioner is mindful of his findings in the previous case and has also considered MHRA's arguments relating to the revised request which is the subject of this decision notice.

21. The Commissioner therefore notes that the request in this case remains a broad, catch-all one for 'all recorded information' held electronically. The complainant has sought to limit its scope to those working on the licencing of and/or pharmacovigilance for COVID-19 vaccines. However, as set out in the request the complainant has still asked MHRA to consider a wide range of formats in which relevant information may be held.

22. In its internal review, MHRA noted that the request was:

> "…not only very detailed, but also very wide with regards to what information you requested. You want all correspondence on not only the safety signals potentially identified but any correspondence on whether and how we communicate these publicly and whether and how we interact with other international regulators."

23. MHRA explained in its submissions to the Commissioner that, for its scoping exercise, it had restricted the search to pharmacovigilance employees and kept the date in line with the complainant's previous request (in which the date of 12 May 2021 was used) as that case demonstrated the exceeded cost limit even at this earlier date.

24. MHRA advised the Commissioner that the pharmacovigilance division responsible for vigilance and risk management for medicines had a total of 139 employees. Their responsibilities included receiving 'Yellow Card'[2] reports and monitoring the COVID-19 vaccines. There were other staff working on the licensing of the COVID-19 vaccines but they were not included in the scoping exercise. MHRA explained that due to the complexity and urgency of the issues surrounding COVID-19 vaccines, there was a significant amount of correspondence and messaging exchanged by MHRA employees.

25. MHRA summarised that when responding to the complainant's request it used as a starting point the 234,536 Yellow Card reports received by MHRA pharmacovigilance employees up to 12 May 2021. Of these, there were 8128 Yellow Cards containing one or more reactions in the Cardiac Disorders System Organ Class (SOC).

26. In order to identify the requested information relating to myocarditis, pericarditis, and other cardiac disorders, MHRA explained to the Commissioner that the following three types of searches were required:

> (1) 55 employees involved in the direct assessment of Yellow Cards would need to search both their Microsoft Outlook and Microsoft Teams accounts for the unique Yellow Card reference number for each of the 8128 Yellow Cards to identify and then extract, any in-scope material.

[2] https://yellowcard.mhra.gov.uk/

(2) all 139 employees would, in addition, need to conduct a keyword search on their Microsoft Outlook accounts. This was considered necessary to identify discussions about myocarditis, pericarditis, and other cardiac disorders that did not include one of the 8128 Yellow Card reference numbers. It may also identify correspondence with public health partners and other regulatory authorities, and correspondence with healthcare professionals and members of the public about the reports. Once identified, MHRA would need to check that the data related to a COVID-19 vaccine and then extract the in-scope material. A keyword search, such as 'myocarditis', would not be sufficient since it may produce results relating to other medicines or vaccines which are not relevant to this request.

(3) Two other electronic platforms would also need to be searched centrally for in-scope material: SharePoint and Documentum.

27. The Commissioner is satisfied that the three different types of searches set out above are reasonably required to identify 'all recorded information' held electronically about suspected adverse reactions to COVID-19 vaccines in relation to myocarditis, pericarditis, and other cardiac disorders. The Commissioner accepts that keyword searches would not be a practical alternative.

28. Dealing with search (1) above in more detail, to search Microsoft Outlook accounts for the unique Yellow Card reference number or hyperlink for each of the 8128 Yellow Cards**,** MHRA explained that in a sampling exercise one employee could search 180 Yellow Cards per hour within its safety database. Each Yellow Card reference number would need to be copied and pasted from a centralised list into the search function within Outlook and MHRA estimated that an employee would complete approximately three Yellow Cards per minute. The Commissioner understands that a Yellow Card report can contain more than one reaction and so it is possible for a Yellow Card report to contain more than one reaction in the Cardiac Disorders SOC.

29. Based on the detail above the Commissioner understands MHRA's estimate to indicate that it would take one employee 45 hours to search their Outlook account. MHRA advised that 55 employees would need to search their Outlook accounts, so 45 hours x 55 employees resulted in an estimate of 2475 hours.

30. In addition, MHRA explained that the 55 individuals involved in the direct assessment of Yellow Cards would also need to search their Microsoft Teams accounts for the unique Yellow Card reference number for each of the 8128 Yellow Cards. As with Microsoft Outlook accounts, MHRA estimated that one employee could search 180

Yellow Cards per hour in Microsoft Teams. This equated to a further 2475 hours for 55 employees, in addition to the 2475 hours already estimated to search Outlook accounts.

31. Dealing with search (2) above in more detail, for 139 employees to perform a keyword search on their Outlook account, MHRA explained that as a starting point 685 keywords were identified as being in-scope. These keywords were taken from a list of Preferred Terms ('PT') within the Cardiac Disorders SOC in the Medical Dictionary for Regulatory Activities (MedDRA)[3].

32. MHRA explained that a PT is a distinct descriptor (single medical concept) for a symptom, sign, disease diagnosis, therapeutic indication, investigation, surgical or medical procedure, and medical social or family history characteristic. MHRA further advised that it would need to consolidate the PT list to establish a shorter list of search terms to ensure unnecessary searches were not included.

33. MHRA estimated that a search using one keyword would take one employee 45 minutes. For example, MHRA said that a search for 'myocarditis' may produce results relating to other medicines or vaccines which are not relevant to this request. Therefore employees who work on a variety of medicines and vaccines would need to carefully identify and extract any information relating to COVID-19 vaccinations.

34. MHRA estimated that, even if the list of 684 MedDRA PTs was reduced by half to 342 terms, it would take each MHRA employee an estimated 256.5 hours to perform a keyword search for the relevant information (ie 45 minutes x 342 MedDRA PTs). The Commissioner notes that this exercise would need to be multiplied by 139 employees.

35. In the Commissioner's opinion, 342 seems an excessive number of keywords to search and no reasonable explanation has been provided for this figure. However, even if both the number of keywords and the search time per word was drastically reduced, the Commissioner accepts that MHRA's cost estimate to perform a key word search would still far exceed the FOIA cost limit of 24 hours.

[3] https://www.meddra.org/

36. For example, if the search time was reduced by to five minutes per keyword and the list of keywords reduced to 10 words only: five minutes x 10 PT words = 50 minutes per employee. 139 employees x 50 minutes =115 hours. MHRA would need to check that the data identified related to a COVID-19 vaccine and before extracting the in-scope material.

37. MHRA told the Commissioner that the final aspect of the search (3) was a central search of SharePoint and Documentum. These searches are not specific to individual employees, and therefore the estimated search time for these platforms would not need to be multiplied by the number of 139 employees. These platforms follow a hierarchical structure and therefore searching for the relevant information would be more efficient. MHRA estimated that it would take one employee one working day (eight hours) to identify and extract the in-scope material.

38. MHRA advised the Commissioner that it did explore automated methods for searching its Microsoft Office 365 systems, such as Outlook and Teams, via a system known as eDiscovery. This would require all data to be loaded to a separate platform, which can only be transferred at 2GB per hour, whilst being monitored by MHRA staff.

39. MHRA advised the Commissioner that it had not estimated the volume of data that would be generated by this search, but to provide context, MHRA explained that a recent Subject Access Request had generated 6.29GB of data relating to one individual. Given that 55 employees' data would need to be uploaded and 8128 Yellow Card numbers searched together with a consolidated list of keywords, the Commissioner accepts that automated methods of searching would likely take in excess of 24 hours for a single defined search across Office 365 systems.

40. The Commissioner has carefully considered MHRA's detailed explanation of its estimate. He considers it possible that MHRA has overestimated some of the search activities, such as the number of keywords required. However the Commissioner remains mindful of the breadth of the request and the large number of staff involved.

41. With this in mind the Commissioner accepts that MHRA has provided a reasonable explanation of its search strategy, and its sampling estimates. Consequently the Commissioner is satisfied that compliance with the complainant's request would significantly exceed the cost limit of 24 hours. MHRA was therefore entitled to rely on section 12(1) FOIA to refuse the complainant's request.

Section 16 – advice and assistance

42. Section 16(1) FOIA provides that a public authority is required to provide advice and assistance to any individual making an information request 'only in so far as it would be reasonable to do so'. Section 16(2) clarifies that, providing an authority conforms to the recommendations as to good practice contained within the section 45 code of practice[4] in providing advice and assistance, it will have complied with section 16(1).

43. In general, where section 12(1) is cited, in order to comply with this duty a public authority should advise the requester how their request could be refined or reduced to potentially bring it within the cost limit.

44. The Commissioner notes that MHRA suggested refining the 'very detailed but also very wide' request in the internal review. It advised the complainant of the information that was already available online about the suspected adverse cardiac reactions associated with COVID-19 vaccines and included links.[5]

45. MHRA also provided a link to its regular public updates in relation to the on-going monitoring of the 'risk:benefit' balance of these medicines which included details of the Public Assessment Reports and the product information which is approved for both healthcare professionals and patients. These pages included announcements through press releases of the latest advice to healthcare professionals and patients.

46. The Commissioner notes that the request which is the subject of this decision notice is almost identical to the request considered in ICO case reference IC-117978-K9G4. In that case the Commissioner found that the advice and assistance MHRA offered the complainant was adequate.

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[4] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/744071/CoP_FOI_Code_of_Practice_-_Minor_Amendments_20180926_.pdf

[5] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions/coronavirus-vaccine-summary-of-yellow-card-reporting

47. The Commissioner further notes that the complainant did refine their request in response to that advice. However, for the reasons set out above, the refined request stills far exceeds the cost limit.

48. Given the wide request, it is not clear to the Commissioner how the complainant could further refine their request. Therefore the Commissioner is unable to identify any further specific advice and assistance that MHRA could be required to provide.

49. In conclusion, the Commissioner considers that the advice and assistance the MHRA offered the complainant to date was adequate. The Commissioner is therefore satisfied that MHRA has complied with its obligations under section 16(1) of FOIA in its handling of this request.

50. Before making a further request the Commissioner suggests that the complainant may wish to review the information already available online about the suspected adverse cardiac reactions associated with COVID-19 vaccines. This may assist them in identifying in more detail the specific information they would like to receive. The request could then be limited to this information, rather than requesting 'all recorded information.'

Other Matters

Internal review

51. As regards the internal review, the complainant also complains that MHRA was late in responding.

52. There is no statutory time set out in FOIA within which public authorities must complete an internal review. The Commissioner considers that a reasonable time for completing an internal review is 20 working days from the date of the request for review. However, in his guidance,[6] the Commissioner has set out his view that the maximum time should not be more than 40 working days.

[6] https://ico.org.uk/for-organisations/guide-to-freedom-of-information/refusing-a-request/#20

53. In this case, the complainant requested an internal review on 8 July 2021.The complainant had to chase the review on 17 September 2021 and did not receive a copy until 21 September 2021, albeit that the letter was dated 9 August 2021.

54. The Commissioner acknowledges that many public authorities were experiencing resource and staffing pressures at the time of the request for review and accepts that the delay may have been due to an oversight. However, MHRA should bear in mind the Commissioner's guidance for future reviews.

Right of appeal

55. 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
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

56. 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.

57. 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 .....

Sarah O'Cathain
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