Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**17 July 2023**
Public Authority:	**Medicines & Healthcare Products Regulatory Agency**
Address:	**10 South Colonnade Canary Wharf London E14 4PU**

Decision (including any steps ordered)

1. The complainant has requested information about Yellow Card reports relating to covid-19 vaccines. The Medicines and Healthcare Products Regulatory Agency (MHRA) refused to provide the requested information, citing section 12(1) (cost of compliance exceeds appropriate limit) of FOIA.

2. The Commissioner's decision is that MHRA was entitled to rely on section 12(1) of FOIA to refuse to comply with the request. However, MHRA breached section 16 of FOIA in failing to provide the complainant with advice and assistance regarding refining their request.

3. The Commissioner requires MHRA to take the following steps to ensure compliance with the legislation.

    - Provide the complainant with advice and assistance, so far as is reasonably practicable, in accordance with its obligations under section 16 of FOIA.

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Request and response

5. On 9 February 2023, the complainant wrote to MHRA and requested information in the following terms:

> "Under the 'Freedom of Information Act 2000', I request disclosure of the following:
>
> For all Yellow Card reports relating to covid-19 vaccines,
>
> a) how many have you followed up with colleagues in primary, secondary, or tertiary care to request further information?
> b) how many of these follow ups have gone unanswered from primary, secondary and tertiary care?"

6. MHRA responded on 9 March 2023. It confirmed that it does hold some relevant information, but the cost of complying with the request would exceed the appropriate limit, therefore it refused the request by virtue of section 12(1) of FOIA.

7. Following an internal review MHRA wrote to the complainant on 12 May 2023. It maintained its reliance on section 12(1) of FOIA.

Reasons for decision

Section 12 – cost of compliance exceeds appropriate limit

8. Section 12(1) of FOIA provides 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 limit" as set out in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 (the Fees Regulations).

9. The appropriate limit is set in the Fees Regulations at £600 for central government, legislative bodies and the armed forces and at £450 for all other public authorities. Therefore, the appropriate limit for MHRA is £600.

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

11. 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 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 in the case of Randall v Information Commissioner & Medicines and Healthcare Products Regulatory Agency EA/2007/0004, the Commissioner considers that any estimate must be "sensible, realistic and supported by cogent evidence". The task for the Commissioner in a section 12 matter is to determine whether the public authority made a reasonable estimate of the cost of complying with the request.

13. Section 12 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 whether there is a public interest in the disclosure of the information.

14. It is important to note that whether or not section 12 of FOIA can be relied upon by a public authority is not affected by what information the complainant considers that the public authority should routinely record, or if a public authority should have a system from which it can readily extract the particular details sought by the request. The Commissioner can only base his decision on the way that the information is, as a matter of fact, held by the public authority at the time when it received the request for information.

The complainant's view

15. The complainant disagreed with MHRA's assertion that the requested data cannot be easily extracted and would require manual review of each case.

16. The complainant argued that they find it difficult to understand why providing the information would exceed the cost limit, stating "as one of the best resourced regulatory authorities in the world, I feel sure your pharmacovigilance software must be sophisticated enough to filter data records to show if/whether a follow up request was sent (and date) and if/whether a response was received (and date). This basic filter should show the information I'm after in seconds".

17. The complainant also made reference to comments made by Dame June Raine about the Yellow Card Scheme in her Blood Inquiry Testimony, which they believe confirm MHRA's ability to filter and extract the

requested information without the need to manually examine every individual Yellow Card report relating to covid-19 vaccines. The statement referred to being "able to develop statistically-based algorithms where the computer system itself would tell us if there was a trend, unusual numbers of reports that we would need to look into quickly". It also referred to the new MHRA SafetyConnect digital technology development programme which "now enables the MHRA to use specialist software to configure smart forms using conditional logic and schedule requests for additional information automatically based on the content of an initial Yellow Card report".

MHRA's position

18. MHRA considered it relevant in the particular circumstances of this case to highlight that the current system in use for Yellow Card reports is the Adverse Drug Reaction (ADR) database, whilst the planned system currently being introduced is known as the adverse incident database.

19. MHRA explained that it had received over 470,000 Yellow Card reports associated with covid-19 vaccines, and to retrieve the requested information each Yellow Card report would need to be manually reviewed to determine whether a request for further information was sent.

20. MHRA had initially advised that the time required to check a single Yellow Card report to determine if it had been followed up was estimated as taking a minimum of 45 seconds. This equated to a minimum of 5875 hours of work. However, on revisiting the matter in response to the Commissioner's investigation, MHRA subsequently advised that two minutes per report was a more accurate estimate. It had reached this estimated figure having dealt with other requests for information which required it to conduct similar searches of the Yellow Card reports. In explanation of why each report would take an average of 2 minutes to examine, MHRA explained that a Yellow Card report is not a single document; each one is a report on the ADR database containing different sections and fields which need to be accessed and viewed.

21. When someone submits a Yellow Card report MHRA asks if the reporter is a member of the public or a healthcare professional. If the individual is a healthcare professional, they must provide their profession from a drop-down list of occupations. MHRA confirmed that it is able to filter Yellow Card reports to identify just those submitted by healthcare professionals. However, this request asks about reports which were followed up with colleagues in primary, secondary and tertiary care, rather than reports submitted by those colleagues. Therefore, the scope of this request requires the consideration of all Yellow Card reports relating to covid-19 vaccines. MHRA explained that this is because a

Yellow Card report can be submitted by a patient but followed up with their doctor (in accordance with MHRA's Yellow Card Privacy Policy[1]). This means that the scope of the request is not restricted to only those Yellow Card reports initially submitted by healthcare professionals.

22. MHRA also addressed both of the statements by Dame June Raine which the complainant referred to in their request for an internal review. Firstly, with regard to being able to develop statistically-based algorithms, MHRA explained that the statistical software referred to is used for signal detection and does not relate to processes for extracting data from the ADR reports or following-up requests for further information. Signal detection is the process by which the data from the reports is passed into the statistical software in order to identify and flag any trends or patterns in the data which require investigation as a potential safety concern.

23. With regard to the second referenced statement relating to the new MHRA SafetyConnect digital technology, MHRA confirmed that this technology does relate to the functionality for requesting follow-ups. It went on to explain that it currently has a programme of work underway, which includes improving and expanding upon tracking of follow-up requests in its new adverse incident management system, however it is currently only suitable for use in a very restricted manner.

24. MHRA went on to explain that the SafetyConnect digital technology development programme enables it to automatically schedule requests for additional information based on the content of an initial Yellow Card report. The technology came into use in December 2020 for the Yellow Card Vaccine Monitor programme (YCVM). The YCVM is a specific data collection programme where individuals can register before receiving a vaccine. Participants in the programme are then actively followed up after receiving a covid-19 vaccine to give information on their experience. The SafetyConnect technology was used only for the YCVM programme until May 2022, not for all Yellow Card data.

25. Since May 2022 the SafetyConnect technology has been rolled out more widely to the Yellow Card website and app, consisting of two elements – 'conditional questions' and 'scheduling follow ups'. The conditional questions functionality has already been used in specific scenarios to collect additional data. However, this particular request for information concerns the functionality for scheduling follow-ups. MHRA explained that this functionality requires further enhancements before it can be

[1] https://yellowcard.mhra.gov.uk/privacy-policy

used on a routine basis, therefore it has not been utilised for reports about covid-19 vaccines outside of the YCVM programme so far. MHRA further explained that at this time there are limitations with the functionality for scheduling follow-ups meaning that it cannot be used routinely as it cannot be applied retrospectively to reports already received, only to newly submitted reports. Finally, the SafetyConnect technology only allows follow-up requests to be sent to registered users of the Yellow Card site, but Yellow Card reports can also be submtted without the individual being a registered user.

The Commissioner's conclusion

26. The Commissioner is satisfied that MHRA has reasonably estimated that the cost of complying with the request would far exceed the appropriate limit.

27. The Commissioner is further satisfied that MHRA has provided a clear and thorough explanation as to why the new technology referenced by Dame June Raine is not able to be utilised to extract the information relevant to this request, meaning that manually examining each Yellow Card report relating to covid-19 vaccines would be the fastest and only way to capture all of the information within the scope of the request.

28. The Commissioner finds that MHRA was entitled to rely on section 12(1) of FOIA to refuse to comply with the request.

Section 16 – duty to provide advice and assistance

29. When refusing a request under section 12, a public authority is required to offer advice and assistance to the complainant where it is reasonable to do so, in accordance with section 16(1) of FOIA. The aim of this advice and assistance is to help the complainant refine their request to one which might be able to be dealt with within the appropriate limit.

30. Section 16(2) clarifies that, providing the public authority conforms to the recommendations as to good practice contained within the section 45 code of practice[2] in providing advice and assistance, it will have complied with section 16(1).

31. MHRA did not provide advice and assistance in either the initial response or internal review response, to help the complainant refine their request

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

to one which might be able to be dealt with within the appropriate limit. Therefore, the Commissioner finds that MHRA breached section 16 of FOIA.

Other matters

32. Whilst the Commissioner has found a section 16 breach in this case, he wishes to acknowledge the positive correspondence he has had with the MHRA during his investigation into this complaint regarding meeting its obligation to provide advice and assistance.

33. MHRA explained that it is currently handling a number of requests from the complainant and, rather than simply advising them to narrow the scope of their request, it would like to engage with them directly in order to understand the information which is of most interest to them. It also wishes to take the opportunity to outline the types of information which are retrievable within the appropriate limit, and to offer advice regarding the scheduling of any subsequent refined requests in order to avoid aggregation and further refusals based on the appropriate limit.

34. The Commissioner considers that if MHRA takes this course of action within 35 days it will have met its obligations at section 16 of FOIA and complied with the step ordered by this decision notice.

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: 0203 936 8963
    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 .....

Victoria James
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