Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**5 March 2024**
Public Authority:	**Medicines & Healthcare Products Regulatory Agency (an Executive Agency of the Department of Health and Social Care)**
Address:	**10 South Colonnade Canary Wharf E14 4PU**

Decision (including any steps ordered)

1. The complainant has requested information about vaccines. The MHRA ("the public authority") refused to comply with the request, citing section 14(1) (vexatious requests).

2. The Commissioner's decision is that to comply with the request would incur a grossly oppressive burden on the public authority and it's entitled to rely on section 14(1) in order to refuse it.

3. The Commissioner does not require further steps.

Request and response

4. On 1 March 2023, , the complainant wrote to the public authority and requested:

> "1a) Is the MHRA maintaining a database of research that has highlighted potential vaccine safety issues? If you do have such a database, can you please share it with me.
>
> b) Has the MHRA seen the research below or any other research that highlights potential vaccine dangers? Notes: A number of studies have highlighted potential vaccine safety issues: e.g. here, here, here and here.

2a) Is the MHRA maintaining a database of people in the UK who have suffered health problems after being vaccinated? If you do have such a database, can you please share it with me, with personal details anonymised.

b) Is the MHRA in contact with individuals who have suffered health problems after being vaccinated, to give them support and monitor the progression of their health issues?

3a) Has the MHRA conducted any clinical research (not statistical) to confirm how many adverse effects reported to the Yellow Card scheme since December 2020 were caused by the vaccines and not just incidental?

b) Can you please share all the research from the MHRA's investigations into these vaccine safety issues/adverse effects? (E.g. the UKHSA has a research portal where I can access all UKHSA-funded research)

4a) Can you explain how the MHRA reviews post-vaccination fatalities?

b) Can you share all these reviews of post-vaccination fatalities since January 2021? Notes: In this document, the MHRA says it undertakes a thorough review of reports with a fatal outcome after vaccination.

5a) Does the MHRA believe single studies that have not yet been independently replicated can be relied on to determine vaccine safety and efficacy? Notes: The clinical trials conducted by Pfizer, AstraZeneca, Moderna, Johnson&Johnson, Novavax, and Valneva to my knowledge, are single studies that have not yet been replicated.

b) Does the MHRA believe observational studies (not randomised and controlled) can be relied on to determine vaccine safety and efficacy? Notes: In the Yellow Card summary for December 2022, three observational studies are cited as evidence for the safety of the vaccines in pregnancy (footnotes 4,5,6).

c) These studies only consider the impact of vaccination on miscarriage, stillbirth, preterm birth. Can you share the evidence that confirms these vaccines won't cause any other health issues over a number of years in children born to vaccinated mothers? The placenta theory is often cited as an answer to this question, but can the MHRA confirm that this theory won't be proven wrong in the coming years?

6a) Can you please give me a full list of all the types of clinical trial documents that were submitted by Pfizer, AstraZeneca, Moderna, Novartis, Johnson&Johnson, and Valenva to the MHRA for review for the COVID vaccines they produced? Notes: Namely: case report forms, clinical study reports, certificate of analysis, protocol, statistical

analysis plan, informed consent form, serious adverse event narratives, electronic individual participant data, investigational medicinal product dossier, investigator's brochure. I can see that the MHRA has published the Public Assessment Report for these vaccines. But I can't see any other data.

b) Of these documents (or any others not named here) which ones were reviewed by the MHRA before giving approval to these vaccines?

c) Can you tell me when all these documents will be published online by the MHRA?

7a) Can you confirm when Phase 4 trials for these six vaccines concluded/are due to conclude?

b) Can you share any documents for the trials that have concluded."

5. The public authority responded on 20 April 2023. It provided answers to the complainant's questions, including explanations regarding the yellowcard scheme.[1]

6. On 30 May 2023 the complainant wrote to the public authority again:

"The response to my FOI 23/159 (attached) does not answer many of the questions I asked. So I am asking for this information again. Please respond to each question (a, b, c) separately, instead of giving a cumulative response.

Please contact me if any clarification is required.

Answer 3:

You said: "Many factors have to be considered when assessing whether a vaccine has caused a reported adverse reaction. When monitoring the safety of medicines and vaccines, MHRA staff carry out careful analysis of these factors."

a) Can you tell me how often these analyses were conducted (weekly, monthly) and how many analyses there are in total?

b) Please share all these analyses with me. I am not asking for the Yellow Card summaries, but the raw data/analyses that were used to compile the Yellow Card summaries from December 2020-present. The analyses of data mentioned in Answer 1: epidemiology studies, data on

[1] The Yellow Card scheme: guidance for healthcare professionals, patients and the public - GOV.UK (www.gov.uk)

national vaccine usage, anonymised GP-based health records, other healthcare data, data from international sources, unpublished studies, and other literature.

Answer 4:

a) You said: "every report with a fatal outcome is reviewed carefully". Can you confirm whether the MHRA follows-up on and analyses every report of a fatality after vaccination individually?

b) These individual analyses of fatalities are the reports that I asked for in my original FOI. Please provide me with the MHRA's analysis of each death. This should amount to over 2,000 reports. I specifically asked for the MHRA's analysis of every fatality, individually, reported to the Yellow Card scheme after COVID vaccination. But you have shared a link to a cumulative summary (the Yellow Card summary). More than 2,000 post-vaccination deaths have been reported to the Yellow Card scheme since December 2020.

c) You also said that the reports of post-vaccination fatalities are cumulatively analysed for patterns or evidence suggesting a causal link. Please provide me with all the raw cumulative statistical analyses of these deaths conducted by the MHRA since December 2020. I am not asking for the Yellow Card summaries, but the analyses/raw data on fatalities that were used to compile the Yellow Card summaries on deaths since December 2020.

d) You said: "All available information is assessed to consider whether the vaccine may have caused the reported death." Please share with me a list of this information that is assessed. Please share the exact details of the information that is assessed. For example, instead of saying "data from international sources", please specify exactly what this data is and share a link to the data where possible.

E.g.:

-Data on vaccine deaths from the CDC: link to data

-Data on vaccine deaths from Israel: link to data

Answer 6:

a) I am looking for a list of all the information that the MHRA assessed in 2020 before approving the COVID vaccines. Please provide this information in the following format:

-Case report forms: Yes it was assessed/No it was not

-Clinical study reports: Yes/No

-Certificate of analysis: Yes/No

-Protocol: Yes/No

-Statistical analysis plan: Yes/No

-Informed consent form: Yes/No

-Serious adverse event narratives: Yes/No

-Individual participant data: Yes/No

-Investigational medicinal product dossier: Yes/No

-Investigator's brochure: Yes/No

-Any other information I have not included in this list: Yes/No

I am not asking just for clinical trial data, but all information, regardless of type, that was assessed by the MHRA. Please do not provide links to websites. While the information provided on these websites is somewhat helpful, it does not give me a cohesive understanding of exactly what data the MHRA assessed. Furthermore, I cannot access the clinical data filed on the European Medicines Agency website because I do not have any login details.

b) Does the MHRA have access to or hold the i) individual participant data + ii) cumulative analysis of post-authorisation adverse event reports for the Pfizer, Moderna, AstraZeneca, and Johnson&Johnson vaccines? If you do, can you please share this information with me."

7. The public authority responded and confirmed it would treat this correspondence as a request for internal review.

8. However, on 20 June 2023 the complainant confirmed they wished their correspondence of 30 May 2023 to be treated as a new request for information.

9. The public authority did so and responded on 15 August 2023, refusing the new request under section 14(1) (vexatious requests).

10. The complainant requested an internal review on 20 August 2023.

11. The public authority provided the outcome to its internal review on 27 October 2023. It upheld its decision to refuse the request under section 14(1).

12. The complainant disputes the public authority's application of section 14(1).

Reasons for decision

Section 14(1) – vexatious requests

13. Section 14(1) of FOIA states:

> "Section 1(1) does not oblige a public authority to comply with a request for information if the request is vexatious."

14. The Commissioner considers that a request can be manifestly unreasonable for two reasons: firstly, if the request is vexatious in the sense that it is an abuse of FOIA process and secondly where compliance with the request would incur an unreasonable burden on the public authority both in terms of costs and the diversion of resources.

15. The public authority is relying on the second theme of vexatiousness in this instance.

16. In order to refuse a single request under section 14(1), the public authority must demonstrate that compliance with the request would impose a grossly oppressive burden. It's a high bar to engage and the Commissioner considers its most likely to be the case where public authorities can demonstrate:

- the requester has asked for a substantial volume of information; and
- there are real concerns about potentially exempt information, which it is able to substantiate, if asked to do so by the Commissioner; and
- the potentially exempt information cannot easily be isolated because it is scattered throughout the requested material.

17. The Commissioner has reminded himself of what is actually being requested here. Parts 3b, 4b and 4c of the request alone ask for 'raw data/analyses used to compile the Yellow Card summaries from December 2020 – present' and 'MHRA's analysis of every fatality, individually, reported to the Yellow Card scheme after vaccination.'

18. In line with a previous decision (paragraph 19)[2], when considering parts 3b, 4b and 4c, the Commissioner is satisfied that section 40(2) (personal information), section 41 (information provided in confidence) and section 38 (health and safety) would all need to be considered.

[2] ic-218885-p4x8.pdf (ico.org.uk)

19. In its internal review outcome, the public authority explained:

> "We have estimated that to locate, open, review to determine if it is in scope, including identifying whether an individual case had been followed up and/or analysed and a recorded comment made by an MHRA assessor would take a minimum of 2 minutes per case, and possibly longer. Extracting the data and then undertaking any redactions would likely increase the time required by an additional 4-5 minutes. Your request would require MHRA to consider in the region of 500,000 case files. Therefore, in the worst-case scenario of 7 minutes per case file, this would equate to 58,333 hours to complete this activity. If we considered 2000 reports of fatalities, this would still exceed 230 hours."

20. Again, taking parts at 3b, 4b and 4c alone, these requests are broad and the Commissioner doesn't see how the public authority could review the information, to prepare it for disclosure, any way other than a manual review of each of the 2000 reports individually and the Commissioner considers the public authority's estimate of 6-8 minutes per report as reasonable.

21. Section 14(1) is a high hurdle to engage but must be guided by the limits outlined in section 12 (cost of compliance exceeds appropriate limit). For the public authority, this limit is 18 hours.

22. When applying section 12, a public authority must provide a reasonable estimate as to how long compliance with the request would take. When applying section 14, a public authority must provide a similar reasonable estimate, bearing in mind that for compliance with a request to represent a 'grossly oppressive' burden, it must exceed the limit under section 12.

23. The estimate that the public authority has provided is 230 hours which is twelve times higher than the limit prescribed in section 12. Even if the public authority became doubly efficient in reviewing each report, compliance with parts 3b, 4b and 4c alone would take 115 hours.

24. The complainant acknowledges that certain parts of their request covers a lot of information but other parts are simply asking for yes/no questions or much less information. The complainant has argued that the public authority should provide what it can within the limit.

25. Like section 12, when refusing a request under section 14(1) because of the grossly excessive burden that compliance with a request would cause, the public authority is under no obligation to partly respond to the request.

26. The Commissioner agrees that compliance would be grossly oppressive. However, this doesn't mean it can automatically be refused. When

applying section 14(1) in this way, a public authority must always balance the burden that compliance with the request would cause with the value and purpose that the request represents.

27. There's always a public interest in public authorities being as transparent as possible. The public authority's role is to regulate medicines in the UK, with this comes the need for transparency and accountability.

28. The complainant's request also focuses on the COVID-19 vaccine. The Commissioner recognises that there are those who have concerns about the safety, efficiency and speed with which these vaccines were developed and authorised.

29. However, the Commissioner must balance the need for transparency against the significant burden that compliance with the request would impose.

30. The public authority operate licensing procedures in conjunction with advice and decisions of expert groups from academic and medicinal backgrounds; including teachers, professors, researchers, and consultants.

31. The public authority has already provided the complainant with a significant amount of publicly available information, and contextual information throughout its handling of the request, that is relevant to their request. The Commissioner doesn't believe that compliance with the request would significantly add to that which is already in the public domain to justify the burden in this case.

Section 16 – advice and assistance

32. When utilising section 14(1) in the way described, a public authority must offer the requester reasonable advice and assistance, with the aim of the requestor submitting a less burdensome request.

33. In its internal review outcome, the public authority advised the complainant to:

- "choose as narrow as possible timeframe which will reduce the number of individual case records that may need to be retrieved, reviewed and redacted.

- give details of a specific document that you believe MHRA will hold, such as an analysis report on a side effect of specific interest associated with a vaccine or a clinical study report for a specific study that has been conducted.

- FOIA is a mechanism to request documented/recorded information or data. You may wish to reconsider the nature of questions posed in an FOI request to limit the scope of a single request which may also reduce the burden on the authority."

34. With the above in mind, the Commissioner is satisfied the public authority has complied with its section 16 obligations.

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.

Alice Gradwell
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF