

## **Freedom of Information Act 2000 (FOIA)**

### **Decision notice**

**Date:** 25 April 2023

**Public Authority:** Medicines and Healthcare Products Regulatory Agency (MHRA)

**Address:** 10 South Colonnade  
Canary Wharf  
London  
E14 4PU

#### **Decision (including any steps ordered)**

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1. The complainant requested from the Medicines and Healthcare Products Regulatory Agency, ('the MHRA'), information relating to decisions and statements made about COVID 19 vaccines.
2. The MHRA initially sought to respond to the complainant's request by providing links to information already published within the public domain. The complainant, however, argued that the MHRA did not disclose the data and evidence which supports the statements which they highlighted in their request. During the course of the Commissioner's investigation, the MHRA changed its position to apply section 14(1) to refuse to respond to the request further.
3. The Commissioner's decision is that the MHRA was correct to apply section 14(1) to refuse to respond to the request.
4. The Commissioner does not require the MHRA to take any steps.

## Request and response

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5. On 31 May 2022, the complainant wrote to the MHRA and requested information in the following terms:

"This is an FOIA request for all documents relied upon by the U.K. government to claim the following statements

- 1) 'They (Covid 19 mRNA vaccines) do not affect or interact with DNA in any way'
  - 2) 'They (Covid 19 mRNA vaccines) are safe and effective'
  - 3) 'They (Covid 19 mRNA vaccines) are safe and effective for pregnant women'
  - 4) 'They (Covid 19 viral vector vaccines) are safe and effective'
  - 5) 'They (Covid 19 viral vector vaccines) do not affect or interact with DNA in any way' 6) 'mRNA never enters the nucleus of the cell, which is where your DNA is kept'."
6. The MHRA responded on 1 July 2022. It provided information, and links to public information in response to each part of the request, explained its reasoning, and highlighted information such as fact checkers where these addressed some of the concerns raised by the request.
7. Following an internal review, the MHRA wrote to the complainant on 29 November 2022. It said that whilst it would generally have applied section 12 to withhold the information, (appropriate limit), it had sought to provide the information which could respond to the complainant's request.

## Scope of the case

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8. The complainant contacted the Commissioner on 16 October 2022, initially about the delay to the internal review response. Following the MHRA's internal review response, they clarified that their concern is that the MHRA has not disclosed the data relied upon when the public statements regarding COVID vaccines highlighted in the request were made.
9. During the course of the Commissioner's investigation the MHRA changed its position to rely upon section 14(1) of FOIA (vexatious requests). It argued that responding to the request further would create a significant and unwarranted burden on it.

10. If section 14(1) is applicable, it negates the requirement for the MHRA to respond to the request further. The Commissioner therefore needs to consider whether section 14(1) was applied correctly.

## **Reasons for decision**

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11. Section 1(1) of FOIA requires a public authority, which receives a request for information, to confirm whether it holds the information, and to communicate that information to the requestor, subject to any exemptions in the Act being applicable.
12. Section 14(1) of FOIA allows a public authority to refuse to respond to a request, as required by section 1, if the request is vexatious. It is designed to protect public authorities by allowing them to refuse any requests which have the potential to cause a disproportionate or unjustified level of disruption, irritation, or distress.
13. The test involved in the application of section 14(1) will usually involve weighing the evidence about the impact on the authority and balancing this against the purpose and value of the request. This is judged as objectively as possible; in other words, would a reasonable person think that the purpose and value are enough to justify the impact on the public authority.
14. However, the Commissioner also accepts that there may be cases where a request could be considered to be vexatious because the amount of time required to review and prepare the information for disclosure would place a grossly oppressive burden on the public authority. This is the position adopted by the MHRA in this case.
15. The Commissioner's guidance on section 14 states that there is a high threshold for refusing a request on such grounds<sup>1</sup>. It says that a public authority is most likely to have a viable case where:
  - the requester has asked for a substantial volume of information and

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<sup>1</sup> <https://ico.org.uk/for-organisations/guidance-index/freedom-of-information-and-environmental-information-regulations/dealing-with-vexatious-requests-section-14/how-do-we-deal-with-a-single-burdensome-request/>

- the authority has real concerns about potentially exempt information, which it will be able to substantiate if asked to do so by the Commissioner, and
- any potentially exempt information cannot easily be isolated because it is scattered throughout the requested material.

#### The complainant's arguments

16. The complainant argues that the MHRA has not provided data to back up its, and the governments, statements that the vaccines are safe and effective. They argued that the MHRA provided links to government generated documents, but that it did not disclose its evidence, including the pre-clinical trial data, and trial data etc, which it refers to in its response.
17. The complainant accepted that they may have asked too many questions, but argued that the MHRA has not answered any single one of them fully by providing the evidence and data explaining how it had reached its conclusion that the vaccines are safe and effective.

#### The MHRA's arguments

18. The MHRA argues that responding to the request further would create a significant burden upon it due to the work which would be involved in locating, analysing, and redacting the information in order that it can be disclosed.
19. It highlighted that, as the request for 'all documents' against each of the six points, this is too broad a request which would include a large volume of information and data within its scope. It said that responding to the request would place a grossly oppressive burden upon it in terms of the time it would require to locate, analyse, and redact exempt information from within the information.
20. It said that, for this reason, in hindsight, it should have refused the request under Section 14 from the outset.
21. It noted that a previous decision notice issued by the Commissioner, IC-167627-X2Z0<sup>2</sup>, related to a similar request, and argued that the section

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<sup>2</sup> <https://ico.org.uk/media/action-weve-taken/decision-notices/2022/4022928/ic-167627-x2z0.pdf>

14 arguments which applied in that case are also relevant to the application of section 14 in this case. It argued that its rationale and approach in engaging Section 14 in this case is similar to that argued in Decision Notice IC-167627-X2Z0.

22. If further argued that it had provided help and assistance to the complainant in formulating their request by providing links to the information which is publicly available and which it had relied upon. It had sought to provide the information which the complainant needed in order to address their concerns.

#### The Commissioner's analysis

23. The MHRA has applied section 14 on the basis of the grossly disproportionate burden responding would place on it.
24. Paragraph 7.14 of the [Code of Practice](#), issued by the Cabinet Office under section 45 of FOIA, makes clear that public authorities should always consider section 12 first in these circumstances. The MHRA said in its initial response that it would normally consider that section 12 was applicable, however, it had decided to provide the information which could respond to the complainant's concerns by responding to each part of the request with the information necessary to understand its position.
25. In estimating the time it would take to respond to a request, section 12 of FOIA does not allow a public authority to include within its calculations the time it would take to analyse, consider, and redact exempt information from the information caught within the scope of the request. The MHRA's argument is that analysing and redacting exempt information from the volume of information caught within the request would be the primary issue which would create a disproportionate burden upon it should it be required to respond to the request. Therefore, the Commissioner accepts that the MHRA has appropriately considered and discarded the application of section 12 under the circumstances of this case.
26. The Commissioner has considered this request in terms of its similarity to the request in decision notice IC-167627-X2Z0. Again, he accepts that vast amounts of information would fall within its scope. He accepts that this voluminous amount of data would need to be thoroughly analysed to determine whether exempt information is contained within it. He also accepts that exempt information would be scattered throughout that information, and that this would make it time consuming to locate, identify and redact that information prior to the remainder being disclosed.

27. The Commissioner has also considered the wider public value of the requested information being disclosed. He accepts that there is a strong public value in the requested information being disclosed. Some members of the public have expressed concerns about various COVID vaccines. A disclosure of the technical data which the MHRA relied upon when making decisions on the safety of vaccines would allow independent experts to conduct their own analysis, and fully scrutinise the decisions made by the MHRA. A disclosure may therefore provide greater public confidence in the decisions taken by the MHRA in this respect.
28. However, the MHRA has provided some information in response to the request, and it sought to provide information which addresses some of the statements raised by the complainant in their request. This weakens the complainant's arguments and lessens the wider public value of disclosure to some extent.
29. Additionally, the MHRA has explained the burden which would be placed on it if it were required to respond to the request in full. It argues that the same arguments and reasoning apply in this case as in decision notice IC-167627-X2Z0. Its arguments were previously examined and accepted by the Commissioner in decision notice IC-167627-X2Z0, and the Commissioner accepts that the burden on the MHRA would be similar in this case, and for the same reasons.
30. For this reason, the Commissioner has decided that, based on his decision in decision IC-167627-X2Z0, the same conclusion should be reached in regard to this request, and for the same reasons.
31. The Commissioner's decision is therefore that the MHRA was correct to apply section 14(1) in this instance.
32. The Commissioner does not require the MHRA to take any steps.

## Right of appeal

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33. 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](mailto:grc@justice.gov.uk)  
Website: [www.justice.gov.uk/tribunals/general-regulatory-chamber](http://www.justice.gov.uk/tribunals/general-regulatory-chamber)

34. 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.

35. 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 .....**

**Ian Walley**  
**Senior Case Officer**  
**Information Commissioner's Office**  
**Wycliffe House**  
**Water Lane**  
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**SK9 5AF**