Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**27 July 2022**
Public Authority:	**Medicines and 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 has requested demographic information about those who have had adverse reactions to the Covid-19 vaccine. The Medicines and Healthcare Products Regulatory Agency ("the MHRA") stated that some of the information was already available elsewhere, but relied upon section 22 (intended for publication) of FOIA in order to withhold the remaining information. During the course of the investigation it subsequently disclosed most of the information.

2. The Commissioner's decision is that the MHRA has failed to obtain the correct objective reading of element [1] of the request and has therefore breached section 16 of FOIA. The MHRA also failed to disclose information within 20 working days and therefore breached section 10 of FOIA.

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

    - Issue a fresh response to element [1] of the request based on the interpretation set out in paragraph 20 of this notice.

4. The MHRA 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 28 July 2021, the complainant wrote to the MHRA and requested information in the following terms:

> "[1] I am writing to request the total number of individuals from Northern Ireland who have died after receiving a Covid19 vaccine, since December 2020 to present.
>
> "[2] I am writing to request the total number of individuals from Northern Ireland who have reported adverse reactions after receiving a Covid19 vaccine, since December to present.
>
> "[3] In addition please provide the above information aggregated by month, vaccine administered either Pfizer/BioTech or Oxford/AstraZeneca: Other, and by age groups below: 0-19; 20-39; 40-59; 60-79; 80+; Age unknown…
>
> "…as Health and Care Number is required for vaccination and also recorded on Death Certificates I hope this information will be relatively straight forward to produce. Also it states on the yellow cards system on the government website that a post code must be provided when reporting deaths or injury (adverse reactions)."

6. The MHRA responded on 26 August 2021. Although it did not explicitly mention section 21, it did explain that information within the scope of elements [1] was available from the Northern Ireland Statistics and Research Agency (NISRA). In respect of element [2], this data was already published on the MHRA's website. In respect of element [3], it stated that the information would be published and therefore it wished to rely on section 22 of FOIA to withhold that information.

7. Following an internal review the MHRA wrote to the complainant on 28 September 2021. It upheld its original position.

Scope of the case

8. The complainant contacted the Commissioner on 8 October 2021 to complain about the way her request for information had been handled.

9. At the outset of his investigation, the Commissioner contacted the MHRA on 15 June 2022 to understand whether the information intended for publication had in fact now been published. The MHRA responded to say that it had not, but pointed to previous decisions issued by the Commissioner explaining why section 22 applied to this information. The

complainant informed the Commissioner that she was not satisfied that wither exemption would apply.

10. The Commissioner contacted the MHRA on 29 June 2022 to point out that the information sought by element [1] appeared to be different to that published by NISRA. He therefore asked the MHRA to either specify exactly where that information was available or to disclose it. The MHRA responded to say that the information it held would engage section 41 of FOIA (actionable breach of confidence).

11. The Commissioner contacted the MHRA a third time on 6 July 2022, he explained that he was sceptical that section 41 would be applicable to the information and asked the MHRA to disclose it. The MHRA issued a fresh response on 15 July 2022. It reverted to its original position: that the information within the scope of element [1] was held by NISRA; but it now disclosed the information it held within the scope of elements [2] and [3].

12. Although the MHRA maintained that the information within the scope of element [1] was reasonably accessible, it now argued that it did not hold the information. Having read the MHRA's reasoning for not holding the information, the Commissioner is not satisfied, for the reasons set out below, that the MHRA has properly understood the request. Given that the MHRA has now had several opportunities to clarify its position, the Commissioner now considers that a decision notice is appropriate.

13. As the complainant has not objected to the information that the MHRA has disclosed in respect of elements [2] and [3], the Commissioner considers that the scope of this investigation is to determine whether the MHRA obtained the correct objective reading of element [1] of the request.

Reasons for decision

14. Section 16 of FOIA requires a public authority to provide advice and assistance to those making, or wishing to make, requests for information.

15. In the Commissioner's view, this duty includes an obligation, on the public authority, to ensure that, before it begins to process a request, it has obtained the correct objective reading of the request. Where a request is capable of being interpreted in more than one way, the public authority should contact the requestor to ensure that it has identified the correct reading.

16. In explaining why it did not hold information within the scope of element [1], the MHRA informed the Commissioner that:

> "We are unable to provide the total number of individuals from Northern Ireland who have died after receiving a COVID-19 vaccine, since December 2020 to present as this is information the Agency does not hold. The Office for National Statistics hold information surrounding **cases in which COVID-19 vaccination was recorded on the death certificate**."

17. The Commissioner does not dispute that the MHRA will not necessarily have access to the information that is recorded on a person's death certificate – however, he does not consider that this the correct interpretation of the request.

18. Whilst the Commissioner accepts that this element of the request contains some ambiguity and that the MHRA's interpretation of the request is a reasonable one, he does not consider that it was the most obvious reading available.

19. The Commissioner considers that element [1] should be read in the context of the correspondence as a whole. Element [2] specifically seeks data on adverse reactions (which would include adverse fatal reactions) to the Covid-19 vaccine. This would indicate that element [2] is aimed at data from the yellow card reporting system the MHRA operates.

20. Whilst the complainant did refer to both yellow cards and death certificates in her request correspondence, the Commissioner considers that a more natural reading of the request would be:

> "I am writing to request the total number of reports from Northern Ireland of fatal adverse reactions after receiving a Covid19 vaccine, since December 2020 to present."

21. The complainant has since confirmed that this reading of her request matches the data she was seeking.

22. The Commissioner accepts that both the MHRA and the complainant have their own interpretation of the request. Both those interpretations are reasonable objective readings of the same request. However, the MHRA should have realised that more than one objective reading was possible and that, having done so, it was under an obligation to determine which objective reading the complainant intended.

23. The Commissioner therefore finds that the MHRA breached section 16.

24. It would appear likely to the Commissioner that the MHRA would hold data on fatal adverse reactions, however as its official stance is that it

does not hold the requested information, the Commissioner is ordering that a fresh response should be provided. The MHRA should confirm whether or not it holds the information in question and, if it does, it should either communicate the information to the complainant or issue a refusal notice that complies with section 17 of FOIA.

Procedural matters

25. Section 10 of FOIA requires a public authority to disclose all non-exempt information it holds within the scope of a request within 20 working days of the request being made.

26. The Commissioner notes in this case that the MHRA initially withheld information before disclosing it during the course of the investigation. As this occurred outside of the 20 working day time limit, the Commissioner finds that the MHRA breached section 10 of FOIA.

Right of appeal

27. 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

28. 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.

29. 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 .....

Roger Cawthorne
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