Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **3 February 2022**

Public Authority: **Medicines and Healthcare Products Regulatory Agency**

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

Decision (including any steps ordered)

1. The complainant has requested information on fatalities by age as a result of having received an approved COVID-19 vaccine. The Medicines and Healthcare Products Regulatory Agency (MHRA) is withholding the information under section 22(1) of the FOIA as it intends to publish it at some future date.

2. The Commissioner's decision is as follows:

    - MHRA is entitled to withhold the requested information under section 22(1) of the FOIA and the public interest favours maintaining the exemption.

3. The Commissioner does not require MHRA to take any remedial steps.

Request and response

4. On 23 May 2021 the complainant wrote to MHRA through the WhatDoTheyKnow (WDTK) website and requested information about the COVID-19 vaccines in the following terms:

> "1. In the section of "weekly summary of yellow card reporting" titled "Events with a fatal outcome" please provide the age groups that the

fatal outcomes occurred per each vaccine. This information should be readily available as it appears in the Interactive Drug Analysis Profile for other medicines.

2. Please provide internal correspondence for the decision to not have coronavirus vaccines available to the public in the Interactive Drug Analysis Profiles."

5. MHRA responded on 21 June 2021, refusing to disclose the information [requested in part 1 of the request] under section 22 of the FOIA. MHRA advised that it intended to publish all suspected reactions reported in association with available COVID-19 vaccines in an interactive format as interactive Drug Analysis Profiles (iDAPs), along with the Adverse Drug Reaction (ADR) summary that is published each week. MHRA went on to explain that the use of iDAPs will enable users to view the data by categories of their choice, such as age, sex and seriousness of reports.

6. Regarding the public interest, MHRA said that it recognised that there is a strong interest in seeing this data and that it accepted that it should not be withheld. But, MHRA said, it wanted to publish the requested data alongside appropriate context and assessment.

7. In his request for an internal review on 22 June 2021, the complainant described his request as being part 1, as given above, but part 2 as being:

"2. Why is there no public Interactive Drug Analysis Profiles for covid vaccination drugs".

The complainant went on to discuss why he considered MHRA could not rely on section 22 of the FOIA to withhold information he is seeking.

8. Following an internal review MHRA wrote to the complainant on 16 July 2021. It re-stated the complainant's request as he had described it in his correspondence of 22 June 2021.

9. MHRA advised the complainant that, in its original response, it had provided him with links to the adverse events which had been identified as a result of its Covid Vaccine Surveillance Strategy. As far as the Commissioner can see, MHRA had not in fact provided that link in its response to the request. However, MHRA provided the link in its internal review response.

10. MHRA went on to say that it had considered the complainant's request for the preparation and provision of redacted reports on events with a fatal outcome broken down by age. MHRA said that, given the volume

of reports, it estimated it would exceed the cost limit under section 12 to prepare the reports in that way.

11. The Commissioner has reviewed the original correspondence as published on the WDTK website. It is not clear to him what reports are being discussed here as, in their correspondence, the complainant does not suggest MHRA redact particular reports. The Commissioner observes that, in any case, the process of redaction is not one that can be included when assessing the cost limit under section 12. Instead, the burden of redacting material is a factor that can be considered under section 14(1) of the FOIA, which concerns vexatious requests.

12. However, MHRA concluded its internal review by upholding its reliance on section 22 of the FOIA to withhold the requested information.

Scope of the case

13. The complainant contacted the Commissioner on 20 July 2021 to complain about the way his request for information had been handled.

14. In light of the complainant's correspondence with MHRA and his complaint and correspondence to him, the Commissioner's investigation has focussed on whether MHRA is entitled to rely on section 22(1) of the FOIA to withhold the information as requested on 22 June 2021, and the balance of the public interest.

15. The Commissioner has dealt with complaints from other individuals who have requested broadly the same information from MHRA and have received a section 22 refusal notice. Since he has already received submissions from MHRA on the matter, the Commissioner did not need another submission from it in relation to this case. MHRA agreed with that approach.

Reasons for decision

16. Section 22(1) of the FOIA says that information is exempt information if:

> (a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not)
>
> (b) the information was already held with a view to such publication at the time when the request for information was made, and

(c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in (a).

17. Section 22 is a qualified exemption which means it is subject to the public interest test.

18. In an earlier submission to the Commissioner, and a subsequent conversation with him, MHRA confirmed that it holds the requested information. Of relevance here is MHRA's 'Yellow Card' website[1]. Through this website MHRA collects and monitors information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices.

19. Interactive Drug Analysis Profiles for a wide range of medicines on the Yellow Card website contain complete data for all spontaneous suspected adverse drug reactions, or side effects, which have been reported on that drug substance to the MHRA via the Yellow Card scheme, from healthcare professionals and members of the public.

20. iDAPs enable people to interact with the data so they can understand more about the types of reactions that have been reported and, at a high level, about who experienced the side effects. The iDAP for each medicine featured on the Yellow Card website report against a number of factors, such as: Sex, Age, Date, Reporter and include the factor referred to in the complainant's request under: 'Seriousness: Fatal; Serious (excluding fatal) and Non-Serious'.

21. However, medicines associated with coronavirus have their own Yellow Card reporting site[2]. At the point of the request, and currently, individuals can submit an adverse reaction report about a COVID-19 vaccine through the coronavirus Yellow Card site but are not able to access the same detailed iDAP data that is available for other medicines on the main site. However, the Coronavirus Yellow Card scheme publishes a weekly summary report of adverse reactions to approved COVID-19 vaccines[3].

22. Following discussion with MHRA and having considered the data that MHRA currently publishes about other medicines on the Yellow Card

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

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

[3] https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

website, the Commissioner is satisfied that the data that the complainant has requested about the COVID-19 vaccines is data that MHRA holds and intends to publish. This is because it holds the same data about other medicines.

23. MHRA notes, correctly, that section 22 of the FOIA does not oblige it to commit to a specific, future publication date. However, MHRA has advised the Commissioner that it expects to publish the data in question by the end of 2022.

24. Turning to (b), MHRA has provided the Commissioner with email exchanges covering the period 23 February 2021 to 2 March 2021. In these exchanges members of MHRA staff discuss technical and presentational issues associated with the publication of the requested data. As such, the Commissioner is satisfied that, at the time of the request on 23 May 2021, MHRA held the data with a view to publishing it at a future date.

25. In correspondence to the Commissioner the complainant has disputed that MHRA intended to publish the information he has requested. He has discussed the difference between MHRA's intention to "seek permission to publish", a phrase it had used in its correspondence with him, and the intention to publish. The Commissioner acknowledges that MHRA's correspondence could have been clearer but, but given the evidence in the email exchanges above, he is content that MHRA did intend to publish the information.

26. The Commissioner is satisfied that the first two criteria at paragraph 16 have been met; MHRA held the requested data with a view to publishing it at some future date and the data was held with a view to such publication when the complainant submitted his request.

27. Finally, the Commissioner has considered (c); whether it was reasonable in all the circumstances to withhold the requested data. The Commissioner's published guidance on section 22 acknowledges that there is some overlap between the factors to consider when deciding what is reasonable, and those which are relevant to the application of the public interest test. However, the Commissioner's guidance goes on to suggest that when determining whether or not it is reasonable, in all the circumstances, to withhold information a public authority should consider whether or not it is sensible, in line with accepted practices, and fair to all concerned. Of relevance here, the guidance advises that an authority may also wish to give thought to whether it is the right decision to manage the availability of the information by planning and controlling its publication.

28. Regarding planning and controlling the information's publication, in its submission to the Commissioner MHRA said it will be developing a more appropriate route to publication in summer 2022 that will allow it to mitigate the risks it has identified. It will begin implementing new systems for providing data across all medical products, including vaccines. This will enable MHRA to produce an improved and more suitable format for publishing data in general. Relevant to this case, alongside raw data MHRA will develop extensive communication materials to manage misuse of data, to mitigate any risks associated with misinterpretation of the data and to manage the resources associated with publishing the data. That is in addition to the continued MHRA response to the pandemic.

29. The Commissioner has taken account of MHRA's position above. The notion of 'fairness' is less of a factor in this case, but the Commissioner accepts too that withholding the information at the time of the request was sensible ie it was not totally illogical, and that it was in line with MHRA's accepted practices. This is because it is MHRA's practice to publish data at the same time as it can provide full and clear and context against each medicine reported on the Yellow Card site as having generated an adverse reaction.

30. The Commissioner considers that it was reasonable in all the circumstances for MHRA to withhold the requested information at the time of the request and the internal review. Since the three criteria at paragraph 16 have been met, the Commissioner's decision is that MHRA was entitled to withhold the information the complainant has requested under section 22(1) of the FOIA. He has gone on to consider the public interest test.

Public interest test

Public interest in disclosing the information

31. In his correspondence to the Commissioner, the complainant has stated that MHRA's intention to publish COVID-19 adverse reactions in iDAP format would be the first time it has provided vaccine adverse reaction information in that format. In the complainant's view, information about COVID-19 adverse reactions must therefore be of "incredibly high public interest" for MHRA to change its reporting policy.

32. The complainant has also argued that MHRA is a publicly funded institution receiving reports from the public for the benefit of the public. Finally, he has noted that the equivalent body in the United States – the Vaccine Adverse Event Reporting System – has provided "this information" as a matter of course, with readable reports since the beginning of the coronavirus pandemic.

33. MHRA noted in its submission that there is a potential benefit and public interest in transparency about the COVID-19 vaccine ADR data.

Public interest in maintaining the exemption

34. In its previous submission to the Commissioner, MHRA has said that, in considering the public interest test, it took into account how releasing data on only those vaccines used in the COVID-19 pandemic could undermine the wider Government public health campaign for widespread COVID-19. MHRA concluded it was a risk to public health and safety, and not in the public interest.

35. MHRA says that the evidence for this risk can be seen, for example, in the termination by the Japanese Government of a human papillomavirus vaccine programme following misinterpretation of published data. In that instance, unsubstantiated claims around safety have been estimated to have the potential to result in eleven thousand deaths[4].

36. It is clear, in MHRA's view, that care must be taken in preparing vaccine data for publication to mitigate catastrophic outcomes. For that reason, MHRA confirmed its stance that maintaining the exemption outweighed any potential benefit in publishing the data [at the time of the request].

Balance of the public interest

37. MHRA says that it carefully weighed the disbenefit of publishing the data without context; the potential for misinterpretation and misuse of sporadic and isolated reports; and the potential subsequent tangible harm against the potential benefit of transparency and wider public interest in publishing the information now (ie at the time of the request). On balance, MHRA says, it remains of the view that the public interest is best served through publishing the data in the future, with contextual narrative. At that point, by providing context to the data and clear guidance on what is being presented, the risk of misuse will be minimised.

38. The Commissioner notes that the main Yellow Card website states that when people review the data within an iDAP it is important to do so in the context of the essential guidance at the bottom of the report (ie the 'context' information) to ensure that they do not misinterpret the data.

[4] https://www.reuters.com/article/us-japan-hpv-vaccine-study-idUSKBN2050K9

39. The Commissioner has noted the complainant's argument about the format in which MHRA's intends to report on the COVID-19 vaccines. He understands – from its submission and a note on the current Yellow Card website that a new website is in development - that MHRA is developing what it considers to be a more appropriate route to publication in summer 2022 that will allow it to mitigate risks it has identified. MHRA says it will begin implementing new systems for providing data across **all medical products including vaccines**. As such, the Commissioner does not consider that how MHRA intends to report on the COVID-19 vaccines is significant. And how another country manages information does not have a bearing on how MHRA manages the information it collects.

40. However, the Commissioner fully appreciates the strong public interest there was, and is, in the COVID-19 vaccines and any adverse reactions people may have experienced after having received one. However, given the significance of the vaccines and the sensitivities surrounding them the Commissioner considers that there is a stronger public interest in MHRA being able to publish the iDAP data for the vaccines, including the information requested in this case, in line with its planned timetable. This will ensure that MHRA has had the time it needs to consider the risks associated with publishing this information; how best to present the information alongside context and guidance so as to minimise the risk of the information being misinterpreted or misused. That is a complex process. As noted, a summary of adverse reactions to COVID-19 vaccines is published weekly and, in the Commissioner's view, that satisfies the public interest in the safety of the vaccines to an adequate degree.

Right of appeal

41. 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

42. 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.

43. 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

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