Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **26 January 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 about adverse reactions to approved COVID-19 vaccines. 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.

    - MHRA's refusal notice was inadequate and did not meet the requirements of section 17(3) of the FOIA.

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

Request and response

4. On 19 March 2021 the complainant wrote to MHRA and requested information in the following terms:

"First of all, I am aware of the information available here: https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions

However, the information linked as above does no report all ADRs data, but only summary data. I request in spreadsheet or database format, e.g., comma-separated-values (CSV) (not PDF format), the full body of all anonymised raw data with the level of details as close as possible to that one available for Interactive Drug Analysis Profile (iDAP) and related CSV files, for all Covid-19 vaccines currently in use in the UK.

Especially to include for EACH event, but not limited to:

SEX
AGE
DATE
REPORTER
REPORT SUBMISSION
ROUTE OF ADMINISTRATION
SERIOUSNESS
SYSTEM ORGAN CLASS"

5. MHRA responded on 19 April 2021, refusing to disclose the information 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. MHRA public interest test position had shortcomings. 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. However, MHRA omitted to give any public interest arguments for withholding the information.

7. Following an internal review MHRA wrote to the complainant on 12 May 2021. It upheld its position but again, did not provide any public interest arguments to support its withholding of the information.

Scope of the case

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

9. The Commissioner's investigation has focussed on whether MHRA is entitled to rely on section 22(1) of the FOIA to withhold the requested information, and the balance of the public interest. He has also considered MHRA's refusal of the request.

Reasons for decision

10. 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).

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

12. In its 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.

13. 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.

14. 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.

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

15. The iDAP for each medicine featured on the Yellow Card website report against a number of factors, including those referred to in the complainant's request: Sex, Age, Date, Reporter etc which he has drawn from the Yellow Card site.

16. 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].

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

18. 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.

19. 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 19 March 2021, MHRA held the data with a view to publishing it at a future date.

20. The Commissioner is satisfied that the first two criteria at paragraph 10 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.

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

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

21. 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.

22. Regarding planning and controlling the information's publication, MHRA says in its submission that it considers that the reasons it gave to the complainant in its April 2021 response are still valid. In addition, MHRA says 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. Specifically in 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.

23. 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 provide full and clear and context against each medicine reported on the Yellow Card site as having generated an adverse reaction.

24. 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 10 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

25. In his complaint to the Commissioner, the complainant has argued that the type of data he has requested – about COVID-19 vaccines and ADRs - is "nothing out of the ordinary" as it is the type of data that MHRA routinely makes available through the Yellow Card website, about other medicines.

26. The complainant refers to COVID-19 vaccines being 'black triangle drugs'; that is, they belong to the class of new medicines and vaccines that are under 'additional monitoring' and are also under 'conditional marketing authorisation'. The full ADR data sent is available [one the main Yellow Card website] for other 'black triangle drugs', such as Brentuximab and it is therefore unreasonable for MHRA to withhold the data associated with the COVID-19 vaccines.

27. The combination of being a 'black triangle drug' with 'conditional marketing authorisation' leads to the COVID-19 vaccines having a higher monitoring need, in the complainant's view. This is because they are new and "incompletely tested" drugs with a "theoretically higher risk of harms to the public". The complainant considers that, as such, there is a public interest in disclosing the data to the public and research community.

28. The complainant also argues that transparency about COVID-19 vaccines data has been advocated in recent medical literature; that the data "originates within the public", is reported by the public and is collected for the public good. Finally, the complainant has referred to it having been pointed out (for example in an article in 'The Telegraph') that MHRA's own analysis of COVID-19 vaccine ADR data has lagged behind similar analyses carried out in some European countries. He considers that disclosing the data would allow independent researchers across the world to analyse it in parallel to MHRA's own artificial intelligence algorithms.

29. MHRA has 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

30. In its 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.

31. 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].

32. 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

33. 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.

34. 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.

35. The Commissioner has noted the complainant's arguments. He 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 stronger public interest in MHRA being able to publish the iDAP data for the vaccines 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.

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

36. As noted, a summary of adverse reactions to COVID-19 vaccines is published weekly and, in the Commissioner's view, this satisfies the public interest in the safety of the vaccines to an adequate degree.

Section 17 – refusal of request

37. Under section 17(3) of the FOIA a public authority that is relying on a qualified exemption to withhold information must, in its refusal notice, state the reasons for claiming that the public interest in maintaining the exemption outweighs the public interest in disclosing the information.

38. In this case, MHRA's refusal notice and its internal review response failed to provide any such reasons. The Commissioner therefore finds that MHRA's refusal of the request breached section 17(3) of the FOIA.

Right of appeal

39. 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

40. 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.

41. 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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