Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 26 May 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 COVID-19 vaccines. The Medicines and Healthcare products Regulatory Agency (MHRA) originally relied on section 22 of FOIA to withhold the information, which concerns information intended for future publication. It subsequently withdrew its reliance on that exemption and is now withholding the requested information under section 40(2) and 41(1) of FOIA, which concern personal data and information provided in confidence respectively.

2. The Commissioner's decision is as follows:

    - MHRA is entitled it withhold the requested information under section 41(1) of FOIA as it is information provided in confidence.

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

Context

4. Through its 'Yellow Card' website[1] MHRA collects and monitors information on safety concerns such as suspected side effects or adverse incidents involving medicines and medical devices.

5. Interactive Drug Analysis Profiles (iDAPs) 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.

6. 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.

7. The iDAP for each medicine featured on the Yellow Card website report against a number of factors, for example: Sex, Age, Date and Reporter.

8. However, medicines associated with coronavirus have their own Yellow Card reporting site[2]. 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].

Request and response

9. On 3 April 2021 the complainant wrote to MHRA and requested information in the following terms:

> "Please can you provide the list of suspected adverse reactions to COVID-19 vaccines received by the MHRA since December 2020 broken down by the following attributes:

[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

i) Vaccine type

ii) Patient age (or age band of a maximum of 5 years)

iii) Patient sex

iv) Patient ethnicity

For clarity:

- This request is for the above attributes to be provided simultaneously for each reaction type - ie, so that it is possible to determine, for example, the number of White British female recipients of COVID-19 Vaccine AstraZeneca in the 35-39 age band who have suffered from an infected dermal cyst following receipt of this vaccine (and not simply the number of White British people, or the number of females, or the number of 35-39 year olds).

- The 'list of suspected adverse reactions to COVID-19 vaccines received by the MHRA since December2020" is those enumerated in the most recent analysis prints published at

https://www.gov.uk/government/publicatio...'"

10. On 5 May 2021 MHRA responded. It refused the request under section 22 of FOIA and said it would advise the complainant when the data was published.

11. MHRA provided an internal review on 9 July 2021. It maintained its reliance on section 22 to withhold the information the complainant has requested, and also discussed the exemption under section 35 (which concerns the formulation and development of government policy).

Scope of the case

12. The complainant contacted the Commissioner on 14 July 2021 to complain about the way their request for information had been handled.

13. In its submission to the Commissioner MHRA confirmed that, on reconsideration, it is no longer relying on section 22 to withhold the requested information but considers section 40(2) and section 41(1) apply. MHRA also confirmed it is not relying on section 35.

14. The Commissioner advised MHRA on 18 May 2022 to communicate its new position to the complainant, which it did on 20 May 2022. In correspondence on 21 May 2022, the complainant confirmed they remained dissatisfied.

15. The Commissioner's investigation has now focussed on MHRA's reliance on section 40(2) and/or 41(1) to withhold information within scope of the request.

Reasons for decision

Section 41 – information provided in confidence

16. Section 41(1) provides that information is exempt if, under subsection (a) the public authority obtained it from any other person and, under subsection (b), disclosure would constitute a breach of confidence actionable by that person or any other person. This exemption is absolute and therefore not subject to a public interest test, as such.

17. In its submission, MHRA says that as outlined in its Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless it is required or permitted to do so by law. The Policy also states that MHRA may receive requests for Yellow Card report data under the Freedom of Information Act. While it is legally obliged to provide some of the requested information, it only provides high-level summary information with all person-identifiable data excluded. Regarding the COVID-19 vaccines specifically, this high-level summary is provided within MHRA's weekly summary of Yellow Card reporting.

(a) Did MHRA obtain the information from another person?

18. Individuals voluntarily submit Yellow Cards to MHRA, on their own behalf or on behalf of others. MHRA publishes broad, high-level summary information of the Yellow Card data that individuals have submitted to it. The complainant has requested more granular information derived from the submitted Yellow Cards. However, both the summary information and the requested granular information is information that MHRA has obtained from other people. As such, the condition under section 41(1)(a) has been met.

(b) Would disclosure constitute a breach of confidence actionable by that person or another person?

19. In considering whether disclosing the information constitutes an actionable breach of confidence the Commissioner considers the following:

- whether the information has the necessary quality of confidence;

- whether the information was imparted in circumstances importing an obligation of confidence; and

- whether disclosure would be an unauthorised use of the information to the detriment of the confider.

20. **Necessary quality of confidence:** The Commissioner considers that information will have the necessary quality of confidence if it is not otherwise accessible, and if it is more than trivial. He is satisfied that the information in this case has that quality. MHRA considers that the data requested can be considered to be personal data and therefore has the necessary quality of confidence. It has confirmed that the information is not otherwise accessible in the format requested. The Commissioner is satisfied that the information has the necessary quality of confidence; it is associated with people's health and, while summary information is published, the granular information underpinning it is not available elsewhere.

21. **Circumstances importing an obligation of confidence:** This limb is concerned with the circumstances in which the confider of information passed the information on. The confider may have attached specific conditions to any subsequent use or disclosure of the information (for example in the form a contractual term or the wording of a letter). Alternatively, the confider may not have set any explicit conditions but the restrictions on use are obvious or implicit from the circumstances (for example information a client confides to their counsellor).

22. The Commissioner accepts MHRA's position here. Given the context and MHRA's published Privacy Policy, he is satisfied that anyone submitting a Yellow Card would reasonably expect that the information they were providing would be treated confidentially.

23. **Detriment to the confider:** The First-tier Tribunal (Information Rights)in Bluck v ICO and Epsom and St Helier University Hospital Trust refers to the fact that "…if disclosure would be contrary to an individual's reasonable expectation of maintaining confidentiality in respect of his or her private information…," this exemption can apply. The Commissioner has accepted that disclosing the information in question in this case would be contrary to the reasonable expectations of the individuals volunteering Yellow Card information. Disclosure would therefore cause detriment to those individuals.

Is there a public interest defence for disclosure?

24. As noted, section 41 is an absolute exemption and not subject to the public interest test. However, the common law duty of confidence contains an inherent public interest test. This test assumes that

information should be withheld unless the public interest in disclosure outweighs the public interest in maintaining the duty of confidence (and is the reverse of that normally applied under the FOIA).

25. The Commissioner recognises that there is strong public interest in the COVID-19 vaccinations and their safety. The Commissioner finds that that interest has been met to an adequate degree by the information that MHRA, and other bodies, actively publish. The Commissioner notes that the complainant did not put forward public interest arguments for disclosure in their request for an internal review, albeit MHRA was relying on section 22 at that point. In their correspondence to him of 21 May 2022, the complainant disputes that section 41 is engaged but has not provided public interest arguments for the information's disclosure.

26. The Commissioner is mindful of the wider public interest in preserving the principle of confidentiality and the need to protect the relationship of trust between confider and confidant. In this case, there is strong public interest in maintaining and perhaps improving the safety of current and future COVID-19 vaccinations through individuals being prepared to voluntarily submit sensitive personal data to MHRA. They will be more prepared to do this if they are satisfied that MHRA will treat the information they provide confidentially.

27. The Commissioner has considered all the circumstances of this case and the nature of the information being withheld under section 41(1). He has concluded that there is stronger public interest in maintaining the obligation of confidence than in disclosing the information. Therefore, the Commissioner finds that the condition under section 41(1)(b) is also met and that MHRA is entitled to withhold the information under section 41(1) of FOIA.

28. Since he has found that the information is exempt from disclosure under section 41(1), the Commissioner has not considered MHRA's application of section 40(2).

Right of appeal

29. 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

30. 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.

31. 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

Cressida Woodall
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