Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**8 April 2024**
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 requested information from the Medicines and Healthcare products Regulatory Agency ('MHRA'), relating to data gathered about a cohort of pregnant women via the Yellow Card Monitor. The MHRA cited section 22 of FOIA and refused to provide the requested information because it was intended for future publication.

2. The Commissioner's decision is that the MHRA was correct to apply section 22 of FOIA at the time of the request.

3. No steps are required as a result of this notice.

Request and response

4. On 13 April 2023, the complainant made the following request for information to the MHRA:

> "On 17th November 2022 you gave a recorded lecture at the All-Wales Therapeutics and Toxicology Centre at the AWMSG 20th Anniversary Conference - The Nicola Wheatley Memorial Lecture.
>
> During that lecture you spoke of the Yellow Card Monitor as an active surveillance of specifically identified cohorts and specifically mentioned a group of 2000 pregnant women who shared their data via the monitor. You were very pleased that this specific group

gives you a denominator to presumably work out more accurate data analysis.

FOI Questions on active surveillance of 2000 pregnant women:

1. How were the pregnant women monitored, how often did they report and how long were they followed for?

2. When were they vaccinated, in which trimester, and how often were they vaccinated and with which vaccine?

3. What was the % of the 2000 pregnancies experiencing:

    a. miscarriage?

    b. still births?

    c. spontaneous abortions?

4. What was the % of the 2000 pregnancies that delivered:

    a. to full-term?

    b. pre-term?

5. Was there any congenital malformation?

6. What were the serious adverse side effects for:

    a. Mother?

    b. Baby?

7. What were the less serious adverse side effects for:

    a. Mother?

    b. Baby?

8. Were there any women followed up whilst breast feeding?

    a. Were any AEs recorded?

    b. Any breast milk discolouration, paresis, suppressed lactation, pain?

9. Did this cohort of 2000 pregnant women influence the MHRA risk/benefit analysis in pregnancy?"

5. The MHRA responded on 19 July 2023. It refused to provide the requested information, citing section 22 of FOIA (information intended for future publication). Instead it provided an interim report that it considered may have been useful to the complainant.

6. On 20 September 2023, the MHRA provided its internal review response and maintained its original position.

Scope of the case

7. The complainant contacted the Commissioner on 23 November 2023 to complain about the way their request for information had been handled.

8. The Commissioner considers the scope of this case to be to determine if the MHRA has correctly cited section 22 of FOIA to withhold the requested information.

Reasons for decision

Section 22 – information intended for future publication

9. Section 22(1) of 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).

10. For the exemption in section 22 to apply, the public authority must have a settled expectation that the information will be published at some future date – even if no precise date has been set.

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

12. In this case, the MHRA has confirmed that it holds the requested information and has explained that, while some information is already in the public domain as part of its regular reporting, it is developing a scientific publication of the Yellow Card Vaccine Monitor. This publication will discuss the totality of the data collected, including the specific points highlighted in the request for information. The MHRA has stated that it intends to publish the information via a peer reviewed journal, as this is the first time Yellow Card Vaccine Monitor ('YCVM') has been used, and it is a novel technology and methodology.

13. The MHRA advised that it did not have a confirmed date for publication but, in its internal review response, it anticipated that the requested information would be published in late 2023 or 2024.

14. The Commissioner has considered the MHRA's position and accepts that in the circumstances, it was reasonable for the MHRA to withhold the requested information under section 22 of FOIA until the future publication date.

Public interest test

15. As the Commissioner is satisfied the exemption was applied correctly in this case, he has next considered the balance of the public interest test.

Public interest in disclosing the information

16. The complainant has argued that there is data in the interim report, provided by the MHRA, that indicates there has been a significant number of adverse drug reactions reported by pregnant women. They argue that the full YCVM information should be published to protect pregnant women and to update the advice given about vaccine safety and side effects.

17. The MHRA recognised the general public interest in transparency, and acknowledged the significant interest in the safety of medicines in those who are pregnant, including vaccines for COVID-19. It advised that it sought to meet this public interest in part through the provision of the interim YCVM report. It added that it already has publicly available information on its position on the use of COVID-19 vaccines for those who are pregnant, and that this position was based on analysis of all Yellow Card data, as well as relevant data from other sources, rather than only on the subset of data for the YCVM to which the request relates.

18. The MHRA accepted that the YCVM data affords the opportunity to consider the results of active surveillance monitoring for the first time and this is an important factor, but it stated that this does not negate the fact that wider reports for the safety topic of specific interest to the

complainant are already easily accessible if they wish to access them via the Yellow Card website.

Public interest in maintaining the exemption

19. The MHRA said that it considers there is a public interest in making information available in a way that allows the presentation of its research to a wide audience with appropriate peer-review. It considers that a strong factor in favour of maintaining the exemption is that this is the first use of the YCVM. It explained that as it is a novel technology and methodology it is important that the paper is initially reviewed externally by independent experts before making it available in the public domain.

20. The MHRA explained that the implementation of the YCVM represents the first time that the MHRA have operated active surveillance in this manner. Given the newness of the approach within a regulatory setting and the relevance of the data to a wider audience, MHRA considered that submission of a scientific journal article for peer review would be most appropriate as it determined this would ensure appropriate levels of independent scientific oversight. The MHRA explained that this is in line with accepted practice for the publication of a paper presenting a scientific methodology. The MHRA considers that this approach is fair to all, as it allows a wider audience, including specialists and members of the public, to consider and assess the paper on its merits and on the basis of independent peer-review.

21. The MHRA pointed out that while the complainant asked for the full YCVM information to be published in their request for an internal review, their original request did not ask for this, and instead focused on specific questions, many of which require "yes" or "no" answers. It explained that the disclosure of aggregate data and answers to narrow questions in isolation without a full discussion of the methods of data capture and the limitations of the data provided could lead to misinterpretation, which could in turn lead to unnecessary concern on the safety of vaccination within a vulnerable population.

22. The MHRA added that a further factor in favour of maintaining the exemption is the availability of safety data on pregnant women already in the public domain to support healthcare professionals and members of the public to make informed decisions regarding use of Covid-19 vaccines. It explained that all data from the YCVM has been continually assessed as part of its surveillance strategy and this is only one of the sources of data that has contributed to its assessment position. It added that information on the safety of Covid-19 vaccines during pregnancy is documented in its Summary of Yellow Card reporting publication which also includes reference to other published studies.

23. The MHRA stated that it: "remains fully committed to publishing the data from Yellow Card Vaccine Monitor and sharing this with the public, and we consider that the time needed for full analysis and the preparation of appropriate scientific commentary, which will then be scrutinised both internally and through external peer review, is of greatest public interest, as it ensures thorough scientific rigour is maintained and applied throughout."

Balance of the public interest

24. The Commissioner recognises the public interest in openness and transparency. He acknowledges the public interest in the safety of vaccines, particularly in vulnerable population groups. However, he also recognises the MHRA's reasoning about its intention to produce a peer-reviewed report encompassing all of the data obtained from the Yellow Card Vaccine Monitor, and the fact that information about the safety of vaccines is already routinely available.

25. Having taken the arguments into account, the Commissioner considers that the balance of the public interest favours maintaining the exemption. There is a public interest in transparency but, in this case, there's greater public interest in allowing the MHRA to publish the requested information to its planned schedule. This is to ensure the public is provided with all the relevant context linked to the data reported and to reduce the risk of misinformation and people becoming concerned unnecessarily.

Procedural matters

27. The Commissioner finds that the MHRA breached section 17(1) of FOIA by failing to provide a section 22 refusal notice within 20 working days of the request.

Right of appeal

28. 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

29. 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.

30. Any Notice of Appeal should be served on the Tribunal within 28 (calendar) days of the date on which this decision notice is sent.

Keeley Christine
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