Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**18 April 2023**
Public Authority:	**Medicines and Healthcare Products Regulatory Agency (an Executive Agency of the Department of Health and Social Care)**
Address:	**10 South Colonnade Canary Wharf London E14 4PU**

Decision (including any steps ordered)

1. The complainant has requested information relating to the covid-19 vaccines. The MHRA refused to comply with the request, citing section 14(1) (vexatious requests).

2. The Commissioner's decision is that the request was vexatious, in that to deal with the request would cause the MHRA a grossly oppressive burden. However, the MHRA breached section 17 (refusal of request).

3. The Commissioner does not require further steps.

Request and response

4. On 30 November 2022, the complainant wrote to the MHRA and requested:

> "Under the 'Freedom of Information Act 2000' and for the following Comirnaty products:
>
> - Comirnaty 30 micrograms/dose Concentrate for Dispersion for Injection (PLGB 53632/0002);

- Comirnaty 30 micrograms/dose Dispersion for Injection (PLGB 53632/0004); and

- Comirnaty 10 micrograms/dose Concentrate for Dispersion for Injection (PLGB 53632/0006).

I request disclosure of:

d. Any and all additional data and/or ongoing/new clinical study data which has come to light since January 2021 and which supported the MHRA's decision to change the status from Conditional Marketing Authorisation to full Marketing Authorisation?

e. In addition to information relating to adults, please provide any and all additional data and/or ongoing/new clinical study data which has come to light since January 2021, for children aged 5-11 and children aged 12-18, which supported the MHRA's decision to change the status from Conditional Marketing Authorisation to full Marketing Authorisation and

f. In particular, any and all additional data and/or ongoing/new clinical study data which has come to light since January 2021 which confirms each product's benefit-risk balance is positive?"

5. The MHRA responded on 7 December 2022; it pointed the complainant to information available in the public domain, via the European Medical Agency's ('EMA') website.[1]

6. The complainant requested an internal review on 12 December 2022. They explained that 'My request was specifically in relation to the MHRA's decision and not the EMA's. So the information provided in your response does not answer my original request.'

7. The MHRA provided the outcome to its internal review on 9 March 2023. It confirmed that 'the EMA's repository does contain clinical data, and the dossier which was submitted to us is the same as that reviewed by the EMA.' However, it explained that it was refusing the request under section 14(1) as to comply with the request would impose a grossly oppressive burden.

[1] Comirnaty | European Medicines Agency (europa.eu)

Background information

8. The Commissioner understands that Comirnaty is more commonly known as the Pfizer vaccine. During the pandemic, the vaccines were granted conditional marketing authorisation ('CMA') from the MHRA.

9. This CMA then turned into the standard marketing authorisation ('MA') and, according to the MHRA, this was done following the 'second annual renewal of Comirnaty, where no new data emerged that would alter the benefit/risk for these products.'

10. The complainant has explained that they wish to 'know and understand exactly what data had been reviewed by the MHRA which had convinced them to convert the status of these marketing authorisations from "conditional" to "full".'

Reasons for decision

Section 14(1) – vexatious requests

11. Section 14(1) of FOIA states:

> "Section 1(1) does not oblige a public authority to comply with a request for information if the request is vexatious."

12. The Commissioner considers that a request can be manifestly unreasonable for two reasons: firstly, if the request is vexatious in the sense that it is an abuse of the FOIA process and secondly where compliance with the request would incur an unreasonable burden on the public authority both in terms of costs and the diversion of resources. The MHRA is relying on the second theme of vexatiousness in this instance.

13. In its internal review outcome, the MHRA explained to the complainant that:

> "…if we were to fully address your request under the provisions of FOIA, we judge that there are two ways we could do this:
>
> 1) Release all data received to us since January 2021, in scope of your request, concerning the three Marketing Authorisations you have asked about.
>
> OR
>
> 2) Review all data received by us since January 2021, in scope of your request, concerning the three Marketing Authorisations you have

asked about, and verify that the exact same data is published in the EMA Repository."

14. Method 1 will essentially provide the complainant with all non-exempt information that falls within the scope of their request. Method 2 would allow the MHRA to confirm, when granting CMA to the vaccines in question, that it took into account the exact same information as the EMA did by comparing the two datasets.

15. In order to refuse a single request under section 14(1), the public authority must demonstrate that compliance with the request would impose a grossly oppressive burden. It's a high bar to engage and the Commissioner considers its most likely to be the case where public authorities can demonstrate:

- the requester has asked for a substantial volume of information; and
- there are real concerns about potentially exempt information, which it is able to substantiate, if asked to do so by the Commissioner; and
- the potentially exempt information cannot easily be isolated because it is scattered throughout the requested material.

16. Looking at the specific information that the complainant has requested (the information that the MHRA took into account when it changed the status of each vaccine from CMA to MA, specifically in relation to children aged 5-11 and 12-18, and further information relating to the benefit-risk balance of the vaccines); this information will be contained within the dossier for each vaccine.

17. The MHRA has advised that each dossier is approximately 2000 pages long. It's also estimated that compliance with method 1), as outlined in paragraph 13, would take approximately 66 hours per dossier. It has further broken this figure down into:

    1 minute reading per page x 2000 pages = 33 hours

    1 minute per page to redact x 2000 pages = 33 hours.

18. That's 198 hours to review, and redact, 6000 pages which are the subject of this notice. Furthermore, the MHRA has indicated that, as the request specifically requests 'Any and all additional data and/or ongoing/new clinical study data, we believe the above would also include data that has been collected via the Yellow Card Scheme.' The yellow card scheme is the system for recording adverse incidents with medicines and medical devices in the UK.

19. As discussed, a public authority must be able to substantiate the concerns that it has about potentially exempt information. The MHRA envisages the following exemptions will need to be considered:

- section 40(2) (personal information) – for any information that might identify MHRA staff or any clinical narratives which could identify patients

- section 41 (information provided in confidence) and section 43(2) (commercially sensitive) – the MHRA has explained that there is a duty of confidence that 'when we licence a product, we produce a Public Assessment Report (PAR) and as part of that process the company to whom the licence has been granted are given the opportunity to make representations on any material included in the draft PAR that they consider to be in confidence or commercially sensitive, we would consider these representations likely to fall within this exemption'

- section 38 (health and safety) – the MHRA has explained that it might consider redactions under this exemption if 'for example, there was some data that would appear prone to being misinterpreted and could result in lower adherence to original & booster vaccination programmes.'

20. The Commissioner has recently[2] accepted the MHRA's application of section 38, section 41 and section 43(2) and considers it likely that the exemptions listed above would apply to some of the information within the dossiers.

21. The MHRA has also explained that 'Dossiers are structured in a way that best supports accessibility for the assessment teams that will review them; this structure does not separate by date. We judge that further work would also need to take place to redact information outside of scope as above which will include additional data in the dossier that does not contribute to risk or benefit, for example administrative data in completed regulatory forms, present and proposed tables, extraneous information about details of suppliers are a couple of examples of what we would expect to find.'

22. The MHRA has explained that 'if we instead conducted a comparison exercise (method 2)) then we judge that any time saved from redaction activities would instead be concentrated on reviewing the data within the repository, noting the data on the EMA Repository will have been anonymised/obscured according to the anonymisation report, and this will complicate the comparison process.'

23. Section 14(1) is a high hurdle to engage but must be guided by the limits outlined in section 12 (cost of compliance exceeds appropriate

[2] IC-166753-N7G6.pdf (ico.org.uk)

limit). For the MHRA, the limit is 24 hours. Looking at paragraph 18, the Commissioner is satisfied that the time it would take to comply with the request, for either method 1 or 2, grossly exceeds this limit.

24. When applying section 14(1), a public authority must always balance the burden that compliance with the request would cause with the value and purpose that the request represents.

25. There is always a public interest in public authorities being as transparent as possible, particularly in relation to the coronavirus pandemic. The Commissioner also recognises that there are those who have concerns about the safety, efficiency and speed with which the vaccines were developed and authorised.

26. However, the Commissioner must remind himself of the purpose of organisations such as the EMA and the MHRA; they operate licensing procedures in conjunction with advice and decisions of expert groups from academic and medicinal backgrounds; including teachers, professors, researchers, and consultants.

27. The Commissioner agrees with the MHRA when it says that the information that it, and the EMA, already publishes about the authorisation of these vaccines, somewhat negates the value of the request and the Commissioner is satisfied that the MHRA was entitled to refuse to comply with the request under section 14(1).

Procedural matters

28. Whilst he acknowledges that the MHRA's original response of 7 December 2022 was provided in good faith, it failed to comply with the requirements of section 17 (refusal of request) in that it failed to confirm that it held any relevant information or state under which exemption it was exempt.

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

Alice Gradwell
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF