Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **13 February 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 4 PU

Decision

1. The Commissioner's decision is that section 14(1) of FOIA is engaged in respect of two requests the complainant submitted to the Medicines and Healthcare products Regulatory Agency (MHRA) for correspondence about COVID-19 vaccine developers. That requests can be categorised as vexatious due to the disproportionate burden that complying with them would cause to MHRA. It is not necessary for MHRA to take any steps.

Request and response

2. The complainant made the following information request to MHRA on 20 November 2021 [**request 1**]:

> "I am writing to make a request for information under section 1 of the Freedom of Information Act 2000.
>
> Please can you provide me with copies of all e-mails sent or received by the head of the MHRA's Biologicals Unit since the start of the COVID-19 pandemic which contain at least one of the following words (spelled with any combination of upper- and lower-case letters):
>
> "- Pfizer
> - BioNTech

- BNT162b2
- Tozinameran
- Comirnaty”

NB: E-mails are not in and of themselves exempt information, though I accept that they may require to be redacted to remove any exempt information contained within them. On that note, it is worth drawing your attention to ICO guidance document "Requests where the cost of compliance exceeds the appropriate limit (https://ico.org.uk/media/for-organisatio...), which states: "the staff time taken, or likely to be taken, in removing any exempt information in order to leave the information that is to be disclosed, often referred to as ‘redaction’, cannot be included as part of the costs of extracting the requested information".

3. On the same day, the complainant submitted the same request [**request 2**] but in respect of the terms:

- Novavax
- Covovax
- NVX-CoV2373
- Nuvaxovid

4. MHRA responded to both requests on 6 December 2021. With regard to request 1, MHRA relied on section 12. In respect of request 2, MHRA neither confirmed nor denied it held the requested information, indicating that it was relying on section 41(2) (information provided in confidence) and 43(3) (commercial interests)of FOIA to do so.

5. On 15 January 2022 the complainant requested an internal review in respect of both requests. However, MHRA’s internal review on 26 May 2022 appeared to discuss only request 1 and emails pertaining to the Pfizer/BioNTech COVID-19 vaccine. It noted that the request is for “all emails” and advised it was now relying on section 14(1) of FOIA to refuse this request.

6. MHRA subsequently confirmed to the Commissioner that it has applied section 14(1) of FOIA to both request 1 and request 2.

Reasons for decision

7. This reasoning covers MHRA’s refusal of the two requests under section 14(1) of FOIA. The Commissioner considers MHRA’s handling of the internal review under Other Matters.

8. Section 12 of FOIA concerns the cost of complying with a request. However, a public authority cannot claim section 12 for the cost and effort associated with considering exemptions or redacting exempt information. However, under section 14(1) of FOIA a public authority is not obliged to comply with a request for information if the request is vexatious. A public authority may apply section 14(1) where it can make a case that the amount of time required to review and prepare the information for disclosure would impose a grossly oppressive burden on the organisation which outweighs any value or serious purpose the request may have.

9. In its internal review of 26 May 2022, MHRA noted that in his published guidance on section 14 the Commissioner advises that "The purpose of Section 14…must be to protect the resources (in the broadest sense of that word) of the public authority from being squandered on disproportionate use of FOIA…" (paragraph 10). MHRA also considered that the guidance below applies to this request and so supports its use of section 14, particularly the first and third bullet points:

> "Even where a request is speculative, fishing for information is not, in itself, enough to make a request vexatious. However, some requests might:
>
> - impose a burden by obliging you to sift through a substantial volume of information to isolate and extract the relevant details;
> - encompass information which is only of limited value because of the wide scope of the request;
> - create a burden by requiring you to spend a considerable amount of time considering any exemptions and redactions; or
> - be part of a pattern of persistent fishing expeditions by the same requester."

10. MHRA explained that it had carried out a sampling exercise in order to understand the burden that the request for 'all emails for 'Pfizer-BioNTech COVID-19 vaccine' would place on it. MHRA said that initially it had covered "parts A and B of the request… (covering two vaccines)" [By "parts A and B" the Commissioner understands that MHRA meant Pfizer and BioNTech in request 1.] MHRA went on to say that "given that at the time of the request, part B related to a pending authorisation, we have updated the sampling exercise to focus solely on the Pfizer vaccine (part A)."

11. MHRA advised that the sampling exercise generated upwards of 1000 emails (1291), and it had estimated the time to make the redactions in

relation to personal information at three minutes per email. This equated to an estimate of 64.55 hours to complete redactions for personal information.

12. MHRA explained that the three-minute estimate per redacted email was not simply an estimate of redaction, which is in principle a simple click and drag exercise. Rather, the estimate included the time to download the email, convert to pdf, mark the redactions, save as a TIFF file (redactions irreversible) and reconvert to pdf. The estimate did not include time for attachments to be reviewed and redacted. It advised there are many attachments, for example long form documents, such as ministerial submissions. MHRA said it would also need to read emails to ensure sensitive information is not included, and to ensure that, amidst the prose, names of external stakeholders and colleagues are not missed.

13. MHRA confirmed it had considered the public interest. It acknowledged that there is a significant public interest in COVID-19 vaccines. It said that accessing information about their regulation is very important, both in terms of organisational transparency and trust building. However, MHRA said, it had dedicated great efforts to drafting and publishing of the public assessment reports for each of the vaccines, and the level of safety related monitoring information available online is extensive. MHRA noted that the amount of time and resources that a public authority has to expend in responding to a request should not be out of all proportion to that request's value and purpose. It considered that providing all emails captured by the scope of the request would be a disproportionate burden on its resources.

14. Finally, MHRA said that as part of the internal review process, in an email to the complainant dated 28 March [2022] it had tried to confirm with the complainant if there was a specific piece of information that they were seeking. It explained that it took this step to establish if the request could be refined in some manner. MHRA said that it believed the complainant's response, which expressed an intention to search through the entire email list, was also suggestive of a fishing expedition and critical to its section 14 decision – complying with the request as framed would result in an exercise that places a significant burden on MHRA's resources.

15. The complainant's two requests, sent to MHRA on the same day, encompass the period from at least March 2020 to November 2021 ie at least 20 months. The requests are also for "all emails" to and from MHRA's Head of Biologicals Unit that contain key words associated with COVID-19 vaccines.

16. The timeframe of the requests covers a period in the UK when the COVID pandemic was at its height. And considering MHRA's role in the pandemic, the Commissioner considers that it is likely that a very great deal of correspondence would be caught by these requests. MHRA's figure of 1000+ for just two elements of request 1 is credible. The Commissioner considers that a high volume of correspondence would also be caught by the remaining elements of request 1, and by request 2. In addition, and as MHRA has noted, many of those emails would also have documents attached to them that would also need to be reviewed and possible redactions made to them – for example for commercial information, information provided in confidence and/or personal data. Furthermore, MHRA has advised that additional staff would need to check that all the material had been appropriately redacted before it was disclosed.

17. Information about COVID-19 vaccines and MHRA's communications with vaccine developers has a value. However, in its submission to the Commissioner MHRA has advised that there is an abundance of information in the public domain on the COVID-19 vaccines which explains the basis for regulatory decisions. For example, public assessment reports (PARs) are written and publicised to provide the public with an understanding of the regulatory decisions MHRA has taken. The PARs are based on the evidence used to support those decisions. MHRA says that the public can search its website for any PAR for a product granted after 2005. As such, the Commissioner understands that any PAR that MHRA held about the vaccines that are the focus of the complainant's requests would have been available at the time of those requests.

18. MHRA goes on to say that a large range of data is also available on its website about on-going safety related monitoring of the COVID-19 vaccines. The Commissioner understands that such information that MHRA held at November 2021 would also have been available at that time.

19. Given the above, MHRA considers that there is a high-level of transparency about how MHRA regulates COVID-19 vaccines. This would not be materially improved by releasing all emails related to the Pfizer and Novavax COVID-19 vaccines. This is primarily because MHRA expects these emails to relate to routine business matters rather than, for example, consequential information about the safety or efficacy of these vaccines. Important data that is pivotal to assessing the vaccines is handled in a defined manner according to the proper regulatory procedures. MHRA therefore does not consider that fulfilling these requests would deliver a material improvement on the current position.

20. The Commissioner is satisfied that any value the complainant's requests have is outweighed by the burden that complying with them would cause to MHRA. Sufficient related information was and is already in the public domain and, as MHRA has noted, spending a minimum of 64 hours preparing and disclosing emails largely concerned with routine business matters is not likely to surface anything new or of note. The burden to MHRA would therefore be disproportionate and the Commissioner's decision is that MHRA is entitled to refuse the two requests under section 14(1) of FOIA.

Other Matters

21. Provision of an internal review is not a requirement of FOIA but is a matter of good practice. The FOIA Code of Practice advises that a public authority should provide a review within 20 working days of a request for one and, in the most complex cases only, in no longer than 40 working days.

22. In this case, the complainant requested an internal review on 15 January 2022 and MHRA did not provide one until 26 May 2022; significantly in excess of the timescale that the Code of Practice advises. The Commissioner has recorded this delay for monitoring purposes.

Right of appeal

23. 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: 0300 1234504
    Fax: 0870 739 5836
    Email: grc@justice.gov.uk
    Website: www.justice.gov.uk/tribunals/general-regulatory-chamber

24. 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.

25. 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
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF