Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**25 September 2023**
Public Authority:	**Medicines & 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 the Medicines & Healthcare products Regulatory Agency (MHRA) seeking further information from named vaccine companies that applied for temporary authorisation for COVID-19 vaccines. The MHRA refused to provide the information citing sections 38 (health and safety) and section 43(2) (commercial interests) of FOIA.

2. The Commissioner's decision is that neither section 38 or section 43(2) is engaged. Additionally the MHRA breached section 10 of FOIA by exceeding the legislative timeframe for responding to the complainant.

3. The Commissioner requires the MHRA to take the following steps to ensure compliance with the legislation.

    - Disclose the information requested at parts a) and b) of the information request.

4. The public authority must take these steps within 35 calendar days of the date of this decision notice. Failure to comply may result in the

Commissioner making written certification of this fact to the High Court pursuant to section 54 of the Act and may be dealt with as a contempt of court.

Background

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5. The MHRA has provided the following background in order to explain some of the terminology:

> "Temporary Authorisation
> This FOI request was limited in scope to the temporary authorisations of the COVID-19 vaccines marketed by Moderna, Pfizer and AstraZeneca.
>
> The decision to approve the supply of these vaccine was taken under Regulation 174 of the Human Medicine Regulations 2012, which enables rapid temporary regulatory approvals to address significant public health issues such as a pandemic. As a note, for Moderna the product was not supplied under the R.174 temporary authorisation although this was authorised; it was supplied subsequently under a conditional marketing authorisation. A conditional marketing authorisation is a later stage of the authorisation process; a conditional marketing authorisation (valid for one year and can be renewed) can be converted into a marketing authorisation (valid for five years and can be renewed), whereas a regulation 174 cannot be."
>
> "Rolling review
> A 'rolling review' is a regulatory process that can be used to complete the assessment of a promising medicine or vaccine during a public health emergency in the shortest time possible. This is done as the packages of data become available from ongoing studies on a staggered basis."
>
> "RFI
> A RFI is a request for information it is part of the regulatory process and enables the regulator to seek further information from the company (Applicant) that has applied for an authorisation. RFIs are part of the process of assessment prior to the authorisation of a medicinal product, in this case a vaccine.
>
> The COVID-19 vaccines subject of this request were assessed as a rolling review, increasing the number of RFIs compared to standard applications. This is because there were several rounds of

assessment, and assessors sent separate RFIs (rather than a consolidated multidisciplinary RFI)…"

6. On 24 January 2023 the complainant wrote to the MHRA and requested information in the following terms:

> "This is a request under the Freedom of Information Act.
>
> I understand that MHRA's process for assessment of a manufacturer's application for authorisation of a medicine for public use includes MHRA requesting further information (eg questions and clarifications) by letter to assist its assessment.
>
> Please can you send me copies of the Request for Further Information letters which MHRA sent to Pfizer, AstraZeneca and Moderna during MHRA's assessment of their submissions leading to Temporary Authorisation of each Covid vaccine.
>
> If you refuse this request under an FOI Exemption, please provide the following information :
>
> a) the document references (inc dates) of those letters
>
> b) how many questions were included in each RFI letter.
>
> If you sent no RFI letters per se because you conducted so-called Rolling Review,s please can you tell me :
>
> c) how many questions/clarifications you asked each of those manufacturers
>
> d) in what form the questions were asked (eg email, telephone, in person)."

7. On 10 May 2023 the MHRA refused the request under sections 41 (information provide in confidence), 43 (commercial interests) and 38 (health and safety) of FOIA.

8. The complainant asked for an internal review on 11 May 2023 but did not challenge the response to the first part of the request (the 'Request for Further Information' letters). The complainant did challenge not having been provided with the alternative information that had been requested in a) and b) – the references including dates of the letters and the number of questions included in each 'Request for Further Information' letter/s.

9. The MHRA provided its internal review on 9 July 2023. It accepted that it should have confirmed that it held information relating to all three parts of the request.

10. The review did not consider the first part of the request as the MHRA's refusal of this part hadn't been challenged.

11. The MHRA applied sections 41, 43 and 38 to the second part of the request - a) and b).

12. The review did not consider the third part of the request – c) and d) but offered an explanation and asked if the complainant wished to go ahead with that part of that request.

13. The review acknowledged that the MHRA should have contacted the complainant earlier to see if they wanted details of queries/clarifications as well as RFIs.

Scope of the case

14. The complainant contacted the Commissioner on 19 July 2023 to complain about the way their request for information had been handled.

15. On 30 August 2023 the MHRA responded to the Commisioner's investigation. It withdrew its reliance on section 41 of FOIA but maintained its reliance on sections 38 and 43(2) of FOIA.

16. The Commissioner considers that the scope of his investigation is to consider the MHRA's citing of sections 38 and 43(2) for withholding the information requested at parts a) and b) of the request. He will also consider any procedural breaches that may have occurred.

Reasons for decision

Section 38 – health and safety

17. Section 38(1) of FOIA states that information is exempt information if its disclosure would, or would be likely to, (a) endanger the physical or mental health of any individual, or (b) endanger the safety of any individual. The exemption must therefore be engaged as a result of endangerment to physical or mental health being at least likely to result.

The Commissioner's guidance[1] states that "The exemption does not necessarily deal with what are usually thought of as health and safety matters, such as establishing the cause of an accident."

18. The Commissioner has been provided with the withheld information.

19. The MHRA had stated in its internal review that –

> "There is a public health risk in members of the public making incorrect conclusions about products based on, for example, the number of information requests. This information could be used to support false messages about vaccine safety that could lead to a reduction in vaccine uptake."

It suggested a parallel scenario, quoting from the Commissioner's guidance[2] in its response to the investigation letter:

> "A health authority is asked to disclose details of research that it has commissioned into the safety of a particular medication.
>
> Disclosure could endanger physical health if the disclosure causes people to stop taking the medication.
>
> The health authority should balance this against the overall public interest in disclosing the information to enable wider public debate about how health authorities ensure the safety of medicines that are prescribed to the public."

20. The MHRA argued that disclosure "would be likely to endanger the physical health of members of the public" as it believes that -

> "disclosure risks promoting discussion of the requested details about RFIs without the necessary context to allow interpretation and assessment; in such a situation, the figures themselves can be presented in a misleading manner in such a way as to reduce confidence in vaccines. This would be likely to have a detrimental effect on the autumn/winter vaccination campaign leading to the situation described in the guidance above where 'disclosure could endanger the physical health if the disclosure causes people to stop taking their medication'."

[1] Section 38 – Health and safety | ICO

21. The MHRA explains that the requested information "consists of reference numbers, dates and the total number of questions…" It describes the information as a "minimal representation of only one aspect in a series of complex and nuanced engagements and communications between the MHRA and the third party applying for a licensing application". The MHRA expresses concern that "greater or fewer numbers of RFIs may lead to presentation of these numbers as equivalent to the quality, safety or efficacy of a medicine". The citing of exemptions to the broader scope (first part) of the original request "was not challenged by the requester". Pursuing the information in parts a) and b) divorces the information -

> "from the crucial contextual information that informs them – in the form of the actual questions asked in the RFI letters – leading to a heightened risk that erroneous and harmful conclusions would be likely to be drawn from disclosure".

22. It states that the details and the numbers are removed from the context of the actual questions and the RFI information itself is "isolated from the other means of engaging and communicating with the third parties that were ongoing at the same time as the RFIs". The MHRA explains that information was requested from third parties in various ways – by letter, email etc. "[T]here were multiple discussions with companies, teleconferences, and oral hearings." Assessment for temporary authorisations is complex involving "multiple staff at MHRA working on the authorisation of the vaccines". Disclosing just the information requested at parts a) and b) "could easily be misleading or misunderstood".

23. The disclosure of this information -

> "could lead to a loss of public confidence in the vaccines, for example, the results could be viewed and presented onwards in such a way as to favour a particular view or position put forward by anti-vaccine proponents; this may lead to potentially wide-spread consequences including but not limited to, risks of lowered adherence to current and future vaccine programmes by the public".

24. Although the MHRA acknowledges that the identity of a requester is irrelevant, it stresses the fact that FOI disclosure is to the world at large. It then points to the Commissioner's prejudice test and the purpose that the information is likely to be used for, rather than the identity and motivation of the requester. The Commissioner notes that the exemption uses the word "endanger/endangerment" rather than "prejudice". The Commissioner's guidance says that 'in light of the

Tribunal decision[3] … the Commissioner has now concluded that the prejudice test that is used in many FOIA exemptions cannot simply be considered as a substitute for the word "endanger"'.

25. The MHRA's expectation would be that

> "any disclosure may be spread through social media and online forums, where, removed from any context, it may lead to premature judgments based on incomplete information which jeopardise public health measures…"

The vaccines that are the subject of the request "are not widely used anymore in the UK, as the virus has evolved, and so later iterations of the vaccine will be more commonly utilised" in later campaigns. The public may not be aware of the differences between vaccines that were authorised earlier and current vaccines. "Any impact on confidence in the vaccines (or a particular vaccine) would likely be extrapolated to the currently used vaccines." The MHRA argues that this provides "a causal link to endangerment fulfilling the conditions of Section 38 because members of the public including clinically vulnerable groups could be deterred from booster vaccines, and in some cases first doses e.g. new arrivals to the UK". Vaccines to be used in the autumn/winter campaign had not been announced at the point the MHRA wrote to the Commissioner.

26. The MHRA pointed to the Commissioner's decision in ic-166753-n7g6.pdf (ico.org.uk) to underline its view about the disclosure of partial information leading to inaccurate comparisons being made between vaccines but acknowledged that the request was different.

27. The complainant challenged the MHRA's arguments. Their view is that the "trials of novel vaccine technologies" were "rushed". The complainant contends that "the number of questions in each RFI letter will provide 'meaningful conclusions about the assessment of the products"'. They suggest that "the more questions MHRA asked in the RFIs, the greater will be public confidence in MHRA's regulatory assessment and the safety of the Covid vaccines". The complainant argues that

> "If MHRA argued that one must also take into the account the other questions asked of each manufacturer in emails, meetings and

[3] EA/2017/0087: Andrew Lownie v Information Commissioner & anor (tribunals.gov.uk), paragraphs 44-45

> phone calls, then the MHRA would, I suggest, do well to publicise the total number not just the number in the RFI letter(s)…"

Their view is that "MHRA need either to release the requested information or be more precise (and less hyperbolic) in their arguments for not releasing it". The complainant contends that "an unjustified lack of transparency and an attempt to avoid embarrassment" prevent the MHRA from disclosing the requested information.

28. To engage this exemption a public authority must demonstrate that there is a causal link between the endangerment and disclosure of the information. It must also show that disclosure would or would be likely to have a detrimental effect on the physical or mental health of any individual. The guidance says that the effect "cannot be trivial or insignificant…even if the risk falls short of being more probable than not, it needs to be such that there may very well be endangerment".

29. Section 38 focuses on information that might pose a risk. He accepts that there is an anti-vaccine movement that may utilise information disclosed about vaccines negatively. However, the Commissioner is not persuaded that the release of this particular information (even at the lower level) provides a "real and actual danger" or is significant enough in terms of a causal link from its disclosure to the physical endangerment of any individual. The MHRA has underlined the inability to contextualise numbers of questions and document references, however, it remains an option for the MHRA to do so.

30. As the Commissioner has decided that the exemption is not engaged he has not gone on to consider the public interest in this matter. However, he has gone on to look at MHRA's citing of section 43(2) to the same information.

Section 43(2) – commercial interests

31. Section 43(2) of FOIA states that information is exempt if its disclosure would, or would be likely to, prejudice the commercial interests of any person, including the public authority holding it.

32. The Commissioner has defined the meaning of the term "commercial interests" in his guidance on the application of section 43 follows:

> "A commercial interest relates to a legal person's ability to participate competitively in a commercial activity. The underlying

> aim will usually be to make a profit. However, it could also be to cover costs or to simply remain solvent."[4]

33. Most commercial activity relates to the purchase and sale of goods but it also extends to other fields such as services.

34. The Commissioner's guidance says that there are many circumstances in which a public authority might hold information with the potential to prejudice commercial interests.

35. The public authority must demonstrate a clear link between disclosure and the commercial interests of either itself, a third party or both. There must also be a significant risk of the prejudice to commercial interests occurring and the prejudice must be real and of significance for it to be successfully engaged.

36. The exemption is subject to the public interest test. This means that, even if the exemption is engaged, the Commissioner needs to assess whether it is in the public interest to release the information.

37. The actual harm that the public authority alleges would or would be likely to occur if the withheld information was disclosed has to relate to commercial interests.

38. The MHRA said that "in the context of a request which asked for the full content of the RFI points" it "would very likely engage both parts of Section 43". Although it sought the views of the authorisation holders, "their key concerns were for the impact of disclosure on public health". Information "drawn from the RFIs alone cannot be used to make reliable comparisons" between the vaccines.

39. The MHRA's view is that "a misrepresentation of the RFI figures would be expected to have a downstream impact on the commercial interests" of a company. If the public was influenced,

> "towards a position of mistrust in relation to the regulator's assessment of the safety, quality and efficacy of the COVID-19 vaccines, and this could cause a reduced uptake of COVID-19 vaccination, a downturn impact on future orders, and also holds the potential for a spill-over effect to other products manufactured by the companies involved".

[4] Section 43 - Commercial interests | ICO

40. It expects these concerns/prejudices to meet the lower threshold of "would be likely" to occur. The MHRA contends that the withheld information is not trivial "and the prejudice to commercial interests to follow tangible and reasoned rationale". It believes "the prejudice to be more than speculative, because third parties have also raised downstream consequences as a topic of concern" and it later gives the example of "deterring others from applying to MHRA, with subsequent effects on patients". To reveal information about the RFI process "could impede the process by which MHRA and applicants have free and frank conversations about their applications". It could impede the flow of information between parties.

41. The MHRA maintained its citing of this exemption "only by way of an interconnected point regarding the grounds for Section 38" and the potential detriment to future vaccination campaigns.

42. The Commissioner considers that the connection between the release of the specific information that has been withheld under parts a) and b) and the commercial interests of the authorisation holders is tenuous. He does not accept that actual harm would ensue if it was released. The exemption is not engaged.

43. For this reason, the Commissioner has not gone on to consider the public interest.

Procedural matters

44. Section 1(1) of FOIA states that:

> "Any person making a request for information to a public authority is entitled –
>
> (a) to be informed in writing by the public authority whether it holds information of the description specified in the request, and
>
> (b) if that is the case, to have that information communicated to him."

45. Section 10(1) of FOIA states that a public authority must respond to a request promptly and "not later than the twentieth working day following the date of receipt".

46. The MHRA took nearly four months to issue a full response to the requester/complainant. Therefore the Commissioner finds that the MHRA breached section 10(1) by failing to respond to the request within 20 working days.

Right of appeal

47. 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

48. 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.

49. 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 .....

Janine Gregory
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