



Neutral citation number: [2024] UKFTT 56 (GRC)

Case Reference: EA/2022/0039

**FIRST-TIER TRIBUNAL
GENERAL REGULATORY CHAMBER
INFORMATION RIGHTS**

Heard: by determination on the papers

Heard on: 11 January 2024

Decision given on: 23 January 2024

Before:

Judge Alison McKenna

Tribunal Member Rosalind Tatam

Tribunal Member Emma Yates

MARCO TULLIO SUADONI

Appellant

and

THE INFORMATION COMMISSIONER

**First
Respondent**

and

**MEDICAL AND HEALTHCARE PRODUCTS
REGULATORY AUTHORITY**

**Second
Respondent**

DECISION

1. The appeal is dismissed.

REASONS

Mode of Hearing

2. The parties and the Tribunal agreed that this matter was suitable for determination on the papers in accordance with rule 32 Chamber's Procedure Rules¹.
3. The Tribunal considered an agreed open bundle of evidence comprising 503 pages. It also considered a closed bundle comprising 13 pages.

Background to Appeal

4. The Appellant made an information request to The Medicines and Healthcare products Regulatory Agency ('MHRA') on 19 March 2021 in the following terms:

First of all, I am aware of the information available here: <https://www.gov.uk/government/publications/coronavirus-covid-19-vaccine-adverse-reactions>. However, the information linked as above does no report all ADRs data, but only summary data. I request in spreadsheet or database format, e.g., comma-separated-values (CSV) (not PDF format), the full body of all anonymised raw data with the level of details as close as possible to that one available for Interactive Drug Analysis Profile (iDAP) and related CSV files, for all Covid-19 vaccines currently in use in the UK.

Especially to include for EACH event, but not limited to:

SEX

AGE

DATE

REPORT SUBMISSION

ROUTE OF ADMINISTRATION

SERIOUSNESS

SYSTEM ORGAN CLASS.

5. MHRA refused to disclose the requested information on 19 April 2021 in reliance upon s. 22(1) of the Freedom of Information Act 2000 ('FOIA')². Following an internal review, this position was upheld and communicated to the Appellant on 12 May 2021. The Appellant complained to the Information Commissioner.

¹<https://www.gov.uk/government/publications/general-regulatory-chamber-tribunal-procedure-rules>

²[Freedom of Information Act 2000 \(legislation.gov.uk\)](https://www.legislation.gov.uk)

6. The Information Commissioner issued a Decision Notice on 26 January 2022, in which the MHRA's reliance on s. 22(1) FOIA was upheld. It also found that the public interest favoured withholding the requested information and that MHRA had failed to address the public interest balancing exercise in its s. 17 FOIA refusal notice but required no steps to be taken. The Appellant appealed to the Tribunal.
7. The requested information has, since the Decision Notice was published, been disclosed by publication. MHRA has submitted that this renders this appeal 'academic' and invited the Appellant to withdraw his appeal. However, he has not done so and accordingly the Tribunal's task is now to decide whether the Decision Notice published on 26 January 2022 was erroneous.
8. We understand that there is a dispute between the Appellant and the Second Respondent as to whether the disclosure which has been made satisfies the full scope of the information requested. We have no jurisdiction to determine that dispute as our statutory task is to consider an appeal against the Decision Notice only.

The Decision Notice

9. The Decision Notice found that MHRA had been correct to rely on s. 22(1) FOIA in refusing to disclose the requested information, but that the Notice issued to the Appellant did not comply with s. 17 FOIA as it did not explain why it was in the public interest to maintain the exemption. It required no steps to be taken.
10. The Decision Notice found that MHRA intended to publish the requested information, but not immediately and not in its raw form, although it would be published later and with some accompanying analysis. The Decision Notice concluded that this was a reasonable thing for MHRA to do.
11. There is some reliance in the Decision Notice on MHRA's submission that in Japan, the release of raw data concerning the HPV (Human Papilloma Virus) vaccine led to vaccine hesitancy with the result that the vaccination programme has been ineffective. The Decision Notice took this submission into account in concluding that the public interest favoured the maintenance of the exemption.

The Law

12. S. 1 FOIA provides that:

(1) 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.

(6) In this Act, the duty of a public authority to comply with subsection (1)(a) is referred to as "the duty to confirm or deny".

13. Section 2(2) FOIA provides that:

In respect of any information which is exempt information by virtue of any provision of Part II, section 1(1)(b) does not apply if or to the extent that—

(a) the information is exempt information by virtue of a provision conferring absolute exemption, or

(b) in all the circumstances of the case, the public interest in maintaining the exemption outweighs the public interest in disclosing the information.

14. Section 22(1) FOIA provides that:

(1) 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 paragraph (a).

15. The date at which the balance of public interest balancing exercise must be assessed is the date on which the public authority refused to disclose the requested information: *Montague v The Information Commissioner and Department for International Trade*: [2022] UKUT 104 (AAC).³ In this case, the relevant date is thus 19 April 2021.

16. The powers of the Tribunal in determining this appeal are set out in s.58 of FOIA, as follows:

“If on an appeal under section 57 the Tribunal considers -

(a) that the notice against which the appeal is brought is not in accordance with the law, or

(b) to the extent that the notice involved an exercise of discretion by the Commissioner, that he ought to have exercised his discretion differently,

the Tribunal shall allow the appeal or substitute such other notice as could have been served by the Commissioner, and in any other case the Tribunal shall dismiss the appeal.

On such an appeal, the Tribunal may review any finding of fact on which the notice in question was based.”

³ [Montague v The Information Commissioner and Department for International Trade: \[2022\] UKUT 104 \(AAC\) - GOV.UK \(www.gov.uk\)](https://www.gov.uk/court-judgments/ukut-104-2022)

17. The burden of proof in satisfying the Tribunal that the Commissioner's decision was wrong in law or involved an inappropriate exercise of discretion rests with the Appellant. The relevant standard of proof is the balance of probabilities.

Submissions and Evidence

18. The Appellant's Notice of Appeal dated 4 February 2022 challenges the Decision Notice's conclusions as to the public interest balancing exercise. He argues in favour of transparency and submits that MHRA's proposed publication of the data with contextual information was at too long a distance in time from its receipt of the raw data. He submits that the Decision Notice reached an erroneous conclusion in relation to the public interest, citing the situation in Japan, where he asserts that the failure of the HPV vaccination programme was due to the Government's withdrawal of support for it as opposed to the public reaction to the publication of raw data alone. He exhibits newspaper and journal articles about the situation in Japan and also articles expressing concern about the delay in publication of the MHRA data.
19. The First Respondent's Response dated 18 March 2022 maintained his analysis as set out in the Decision Notice. It is submitted in particular that s. 22 FOIA requires there to be no specific date or time period by which the intended future publication of the information would take place, and so the Appellant's ground of appeal in this regard cannot succeed.
20. The Second Respondent's Response dated 18 May 2022 confirmed that the requested information was due for publication by the end of 2022, in a new computer format and alongside contextual information. It was submitted that s. 22(1) FOIA was engaged and that the public interest favoured awaiting publication until the requested information could be published in an appropriate format.
21. The Second Respondent also relied on a witness statement from Dame June Raine DBE dated 3 May 2022. She is the Chief Executive of MHRA. She confirms that the data requested was not available, nor suitable, for publication in the iDAP format requested (this format being used by MHRA for alleged adverse reactions to prescribed drugs, but not for suspected adverse reactions to a vaccine), and that the new computer system was designed for MHRA to comply with its obligations under GDPR. She reiterates that publication of raw data without contextual information carried a risk of stoking vaccine hesitancy.
22. The Appellant did not file a Reply.
23. We have considered the withheld information itself in a closed bundle, which also contains correspondence between MHRA and the Information Commissioner's Office which is revelatory of it. We 'gist' it for the benefit of the Appellant here as follows: it contains all the raw data reports of vaccination responses. We have not found it necessary to refer to this information in a closed annexe to this Decision.

Conclusion

24. We find that the evidence which MHRA submitted to the Information Commissioner shows that there was a settled intention to publish the requested information at a later date, when it could be contextualised.
25. The unchallenged evidence of Dame June Raine DBE confirms this and explains that there was a decision not to publish raw information regarding the coronavirus vaccination programme due to the risk of misuse of the data, the ‘work in progress’ for preparing, testing and implementing the new computer system, and that it would be an unwise allocation of resources to prepare this vaccine raw data for the old format concurrently with preparing it for the upgraded, safety-responsive more comprehensive functionality being installed. We are satisfied that s. 22(1) FOIA was thus engaged. However, we agree with the Decision Notice that MHRA failed to address the public interest test in its response to the Appellant.
26. We agree with the Decision Notice that the public interest, assessed at the date when the information request was refused by MHRA, lay in withholding disclosure of the raw data until such time as it was possible to place it within a narrative context. This was especially the case in circumstances where MHRA had to balance the public interest in transparency against the risk of contributing to vaccine hesitancy in the context of a global pandemic.
27. We are unable to reach a conclusion about the situation regarding the HPV vaccination in Japan, but we find that we do not need to do so in order to decide this appeal. We are satisfied that the public interest favoured the maintenance of the exemption in this case notwithstanding the disputed situation in Japan, about which we are in no position to make a finding of fact.
28. In all the circumstances we discern no error in the Decision Notice and so we dismiss this appeal.
29. As we have explained, the post-Decision Notice dispute between the parties as to the extent of the disclosure which has subsequently been made is beyond our remit, which is to consider the Appellant’s appeal against the Decision Notice only. We note that whether the requested information has been disclosed in a format “*as close as possible*” (see paragraph 2 above for the wording of the request) to something else is unlikely to be capable of resolution by this Tribunal in any event.

(Signed)

JUDGE Alison McKenna

DATE: 17 January 2024

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