

## **Freedom of Information Act 2000 (FOIA)**

### **Decision notice**

**Date:** 11 October 2022

**Public Authority:** Medicines and Healthcare products Regulatory Agency

**Address:** 10 South Colonnade  
Canary Wharf  
London  
E14 4PU

#### **Decision (including any steps ordered)**

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1. In a two part request, the complainant has requested information about staffing associated with COVID-19 vaccines and the use of consultancy staff. The Medicines and Healthcare products Regulatory Agency (MHRA) provided some relevant information and advised it does not hold the specific information requested.
2. The Commissioner's decision is as follows:
  - On the balance of probabilities, MHRA has disclosed all the information it holds that is within scope of the request and has complied with section 1(1) of FOIA.
  - MHRA's response did not fully comply with section 10(1) as it did not confirm it does not hold some of the requested information within 20 working days.
3. The Commissioner does not require MHRA to take any corrective steps.

## Request and response

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4. On 8 July 2021 the complainant requested information of the following description:

"I am writing to make a request for information under section 1 of the Freedom of Information Act 2000.

**[1]** Please can you confirm how many MHRA members of staff (permanent and temporary) are currently working, or have worked, either full-time or part-time, on:

- a) The licensing of COVID-19 vaccines,
- b) Pharmacovigilance for COVID-19 vaccines, and
- c) Any other matter related to COVID-19 vaccines.

Please provide the numbers separately for (a), (b) and (c). For each of (a), (b) and (c), please can you confirm (simultaneously):

- 1) How many members of staff fall into the category of (i) Senior Civil Servant (excluding Directors or above) and (ii) Director or above.
- 2) The split of staff between MHRA Divisions.

Eg, "5 members of staff are currently working, or have worked, on (a) (the licensing of COVID-19 vaccines). Of these 5 members of staff, 4 work in the 'X' Division (of which 1 is a Senior Civil Servant and none are Directors or above), and 1 works in the 'Y' Division (of which none are either Senior Civil Servants or Directors or above)."

**[2]** Finally, please can you separately confirm whether MHRA is using any consulting, professional services or similar firms to support with work related to COVID-19 vaccines, and, if so, how many full-time equivalents (FTEs) from these firms are currently working, or have worked, on this topic, subdivided into matters (a), (b) and (c) listed above."

5. On 5 August 2021 MHRA responded. MHRA advised it was conducting almost real time safety surveillance of all COVID-19 vaccines currently used in the UK. It said that many people across the whole Agency contribute to the work on licensing and monitoring the safety of COVID vaccines and so it was not possible to give an exact number. However, MHRA confirmed that in the Division responsible for vigilance and risk management for medicines, there were a total of 137 full time equivalent (FTE) staff.

6. The complainant requested an internal review on 11 August 2021.
7. MHRA provided an internal review on 15 November 2021. It again advised it does not hold accurate data on the number of staff working on COVID-19 vaccines at any defined interval. But MHRA could advise that there were 192.9 FTE staff in its Licensing Division, which is responsible for regulatory approval of the COVID-19 vaccines. MHRA explained that staff primarily working on regulatory assessments of COVID-19 vaccines are part of the Biologicals Unit (a sub-unit of the Licencing Division). It said that the Biologicals unit includes 14.6 FTEs. MHRA also noted that wider resources in the Licensing Division can be made available to assist evaluation of COVID-19 vaccines as necessary and if appropriate.
8. Finally, MHRA noted the contribution made by National Institute for Biological Standards and Control scientists, the Commission on Human Medicines, and Expert Groups.

### **Scope of the case**

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9. The complainant contacted the Commissioner on 20 November 2021 to complain about the way their request for information had been handled.
10. It appeared to the Commissioner that MHRA had addressed the first part of the request but not the second. When he wrote to it for its submission on 27 July 2022, he asked MHRA to confirm its final position on both parts of the request.
11. Having received the submission from MHRA, the Commissioner's investigation has focussed on whether it holds further recorded information within scope of both parts of the complainant's request and whether its response complied with section 1(1) and section 10(1) of FOIA.

### **Reasons for decision**

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#### **Section 1 – general right of access to information held by public authorities**

12. Under section 1(1) of FOIA anyone who requests recorded information from a public authority is entitled under subsection (a) to be told if the authority holds the information and, under subsection (b), to have the information communicated to them if it is held and is not subject to an exemption.

13. In part 1 of their request, the complainant has requested: [at 8 July 2021] the number of MHRA staff working, or who have worked, on various aspects of the COVID-19 vaccines, the seniority of those staff members and the Divisions in which the staff work.
14. In its submission, MHRA has noted that it has recently begun an initiative to improve its understanding of resourcing versus activities. But it has confirmed that, at the time of the request, in line with the records it holds it had provided the highest level of granularity of the data on its staffing numbers that it could, at the point of its internal review.
15. MHRA says it searched for relevant information by emailing relevant unit managers (eg Healthcare Quality and Access, Safety and Surveillance and Human Resources) to check if it held electronic systems / databases, or a register of staff time spent dedicated to COVID-19 related activities.
16. MHRA says it was informed early on that it does not keep formal records on duties / time allocated to working on COVID-19. MHRA has subsequently also been advised that its HR system "...does not record for instance who is working on x project/piece of work so it can't be collected from the HR system perspective." Much of the resource related to COVID-19 was on an ad-hoc basis / as and when a specific need arose. Therefore, the figures it provided to the complainant were estimates, and this was stated in the internal review.
17. COVID-19 related activities spanned different departments but in terms of the Biologicals Unit, MHRA re-affirmed the following having reconsidered the request as a result of this complaint: "All the Biologicals assessors work on multiple projects in parallel and at present we have no system to track the time spent on each individual project. At peak periods assessors may have put other work to one side, but we did not have a COVID-19 team and a non-COVID-19 team. Therefore, the best we could do was to give staff numbers and estimates."
18. MHRA considers that beyond repeating checks with relevant senior colleagues that were carried out when dealing with the request and this complaint to the Commissioner, there does not appear to be any other avenue to explore. MHRA says this was not a typical FOI request eg for a set of documents that could be searched. Similarly, checks for internal correspondence would not be suitable as many tasks will have been assigned outside of email correspondence. Moreover, there is no reliable list of search terms that would retrieve comprehensive or reliable results.

19. The Commissioner considers that the internal discussions and searches that MHRA has carried out are relevant and appropriate. He accepts MHRA's explanation that, at the time of the request and currently, MHRA does not have a central database that records what staff and how many were carrying out, or had carried out, COVID-19 vaccine related activities at any point in time. It was therefore not possible for MHRA to provide the complainant with the specific information they requested in part 1 of their request on 8 July 2021. The Commissioner is satisfied that MHRA does not hold that information and its response to part 1 complied with section 1(1) of FOIA.
20. In part 2 of their request, the complainant first asked whether MHRA used consultancy or similar services on COVID-19 work.
21. MHRA did not clearly address this part in its correspondence to the complainant. In its submission to the Commissioner MHRA has confirmed that it did not utilise consulting services during the MHRA COVID-19 response. As such, the remaining questions the complainant asked about consultancy are not relevant. MHRA has now effectively confirmed through its submission that it does not hold information within scope of part 2 of the request. The Commissioner accepts that is the case and finds that MHRA has now complied with section 1(1)(a) with regard to part 2.

### **Section 10 – time for compliance**

22. Under section 10(1) of FOIA a public authority must comply with section 1(1) promptly and within 20 working days following the date of receipt of the request.
23. In this case, MHRA did not comply with section 1(1)(a) in respect of part 2 of the request within the required timescale ie it did not confirm it does not hold relevant information. MHRA therefore did not fully comply with section 10(1).

## Right of appeal

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24. 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](mailto:grc@justice.gov.uk)  
Website: [www.justice.gov.uk/tribunals/general-regulatory-chamber](http://www.justice.gov.uk/tribunals/general-regulatory-chamber)

25. 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.
26. 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**  
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**SK9 5AF**