Reference: IC-254831-S5N2

Freedom of Information Act 2000 (FOIA)

Decision notice

Date:	**30 November 2023**
Public Authority:	**Medicines & Healthcare Products Regulatory Agency (MHRA)**
Address:	**10 South Colonnade Canary Wharf E14 4PU**

Decision (including any steps ordered)

1. The complainant has requested information demonstrating conditions of authorisation for a Pfizer vaccine were met. The MHRA refused the request under section 12 of FOIA as it would exceed the appropriate cost limit to comply.

2. The Commissioner's decision is that the MHRA has correctly applied section 12 to refuse the request and has also complied with section 16 of FOIA by providing advice and assistance to refine the request.

3. The Commissioner does not require further steps.

Request and response

4. On 16 February 2023 the complainant wrote to the MHRA and requested information in the following terms:

> "Please could you confirm whether Pfizer Vaccine BNT162b2 complied with the CONDITIONS OF AUTHORISATION UNDER REGULATION 174 in full?
> Yes or no.

Please provide evidence that each of the requirements outlined in this document ARCHIVE: Conditions of Authorisation for COVID-19 Vaccine Pfizer/BioNTech (Regulation 174) - GOV.UK (www.gov.uk) was compiled with."

5. The MHRA refused the request under section 12 of FOIA on 25 May 2023. The complainant disputed this position, particularly as answering the first part of the request simply required a yes/no answer.

6. Following an internal review the MHRA wrote to the complainant on 7 August 2023. It stated that it had aggregated both parts of the request and it was still being refused under section 12 of FOIA.

Scope of the case

7. The complainant contacted the Commissioner on 27 August 2023 to complain about the way their request for information had been handled.

8. The Commissioner considers that the scope of his investigation is to determine if the MHRA has correctly aggregated the request and refused it on the grounds of section 12 of FOIA.

Reasons for decision

Section 12(4) aggregation of related requests

9. When a public authority is estimating whether the appropriate limit is likely to be exceeded, it can include the costs of complying with two or more requests if the conditions laid out in regulation 5 of the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 ("the Fees Regulations") can be satisfied.

10. Section 12(4) allows for requests to be aggregated it they are made by one person or different persons acting in concert. Regulation 5 of the Fees Regulations further adds the requests must relate to the same or similar information and be received within sixty consecutive working days of each other.

11. The Commissioner notes the requests aggregated by the MHRA here are from the same complainant, made on the same day and for information on the same issue – a specific vaccine and whether it met conditions for authorisation. He therefore finds the MHRA were entitled to rely on section 12(4) of FOIA to aggregate the requests.

Section 12 – cost of compliance exceeds the appropriate limit

12. Section 12(1) states that a public authority is not required to comply with a request for information if it estimates that the cost of doing so would exceed the appropriate cost limit.

13. This limit is set in the Freedom of Information and Data Protection (Appropriate Limit and Fees) Regulations 2004 ("the Fees Regulations") at £600 for public authorities such as the MHRA. The cost must be calculated at a flat rate of £25 per hour. This means that the MHRA may refuse a request for information if it estimates that it will take longer than 24 hours to comply with it.

14. When calculating the estimate, the Fees Regulations state that a public authority can only take into account the costs it reasonably expects to incur in:

    - determining whether it holds the information;
    - locating the information, or a document containing it;
    - retrieving the information, or a document containing it; and
    - extracting the information, or a document containing it.

15. The Commissioner considers that the estimate must be reasonable. Following the approach of the First Tier Tribunal in EA/2007/0004 a reasonable estimate is one that is sensible, realistic and supported by cogent evidence.

16. In determining whether the MHRA has correctly applied section 12 of FOIA in this case, the Commissioner has considered the MHRA's explanations provided to him during the investigation.

17. By way of background, the R174 Temporary Authorisation concerns specific batches of the COVID-19 vaccine BNT162b2. Conditional Marketing Authorisations (CMA) and R174 authorisations are issued in exceptional circumstances and can be granted where clinical data is incomplete but a requirement for this at a later stage can be imposed.

18. In the hyperlink provided within the complainant's request there is a list of conditions or requirements imposed by the temporary authorisation that were required to be met over time.

19. It is this list of conditions and the evidence showing each was met that is the main subject of the request. The list of conditions consists of 65 points. These cover a range of areas from product quality and information, instructions for use and clinical activities to deployment, supply chain and distribution. The MHRA argues that as the request asks

it to provide information to 'evidence' each point, this is the equivalent of one request containing 65 questions, each asking for information to demonstrate the condition or requirement has been met.

20. The MHRA stated that due to the number of requirements and the variation in the retrieval exercises needed across all of them it would not be a straightforward exercise and an estimate could not be calculated using a simple formula of x number of records would take x time per record to locate/extract.

21. The MHRA did begin to look at identifying information in scope and collating this and it took in excess of eight hours. This was approached in several stages, firstly reviewing the list to determine what is a condition and what in the MHRA's remit. Then the MHRA determined where information relating to that requirement might be held and what elements of that information would demonstrate that the requirement was or wasn't met. The final stage involved retrieving and extracting information. This had to be downloaded or removed from broader documents/files and the information covers different database systems and software.

22. For the first activity – reading through and identifying whether each condition/requirement would have any information that could be viewed as evidence - the MHRA states it took over two hours. It then spent a further six hours making enquiries with colleagues and discussing what information would be 'evidence'.

23. The MHRA explained that the 'stage two' activities were necessary to determine if information was held for requirements on the list or if any would be the responsibility of other parties, for example NHS England or the UK Health Security Agency. The MHRA considered even for those requirements it did not have responsibility for it needed to consider whether it had received information or information had been shared with it and was therefore held for the purposes of this request.

24. To comply with the request in full the MHRA would need to consult with colleagues across three departments across a range of roles and disciplines due to the nature of the regulation of medicines and the structure of the organisation. It would need to contact clinical assessors, inspectors and specialists in pharmacovigilance.

25. Information in scope of the request would be spread across multiple locations, each area of the MHRA has their own SharePoint site where some information in scope will be stored. As well as this the MHRA has a licensing database which has different areas for different activities ie inspections, safety reports. Searching these areas would require different members of staff with different permissions and knowledge to

access the information and understand the conditions sufficiently to know what evidence could be held that needs to be retrieved.

26. The MHRA also states information could be held in individual email accounts or in group mailboxes and these would need to be searched. In 2020/2021 the MHRA had a different operating structure and a number of individuals that would have been involved in R174 products have since left the organisation so IT may need to be involved in searching any archived mailboxes.

27. To give a specific example of the time and complications involved the MHRA have explained in more detail the steps need to locate/extract information in relation to just one of the quality conditions:

    "Further batches are authorised for supply, subject to batch specific approval by MHRA and providing that the full product lifecycle is in compliance with the conditions specified above in relation to batch EJ0553"

28. It explained that the batch specific process in place of R174 batches meant that checks and evidence needed to be considered per batch, with each batch requiring individualised documentation. This means multiple searches for the type of document are required for each batch. A search of one mailbox located more than 50 R174 letters. Of these letters some amended the conditions as initially published, this meant that a batch at the point of testing and release would be under the conditions in force at that point but batches released later may have had to meet adjusted conditions. The MHRA argued this made gathering 'evidence' to demonstrate this condition had been met more difficult as a batch tested and placed on the market in one month may be under different conditions than a batch tested and placed on the market a month later. As such the information that needs to be located to demonstrate if the condition has been met could differ from batch to batch.

29. A team at the MHRA did undertake an exercise to retrieve relevant evidence for the testing of each batch and estimated it would take just over an hour for each batch.

30. The MHRA has also provided the Commissioner examples of difficulties it would have in regard to other conditions. For example:

    "Ensure that any participants in study c4591001 that choose to be unblinded and then have a COVID-19 vaccination if they are on placebo arm, should have an end of study visit including immunogenicity assessment (including anti-N antibodies) and also NAAT. This is to ensure that they have a complete status before they become unevaluable for the control arm."

31. This related to a specific point within a clinical study report submitted to the MHRA by Pfizer. The document contained numerous papers with hundreds of thousand of pages. The term 'unblinded' appeared hundreds of times in the report. The MHRA explained each return on this term would then need to be viewed and read to determine if it's relevant.

32. The MHRA provided further specific examples to the Commissioner relating to other conditions, each demonstrating the complexities of identifying relevant information. It is clear to the Commissioner that this request is not straightforward as it contains multiple elements, covering a broad range of information across various systems and departments.

33. The MHRA has not been able to provide a specific total time estimate due to the vast amount of information involved but has provided the time taken to conduct sampling exercises relating to 10 of the conditions. The time taken was just over 16 hours to locate and extract a portion of the information for the 10 conditions.

34. Based on this the time required to comply with the request in full would be significantly in excess of 24 hours. Whilst the Commissioner considers it would not be as extensive to locate the 'evidence' to demonstrate compliance with every condition, it is clear that some of the conditions would require significant work to locate and extract information relevant to the request.

35. The Commissioner considers the MHRA has provided thorough and detailed explanations as to why this is not a straightforward request and as such he finds that to provide the requested information would exceed the appropriate limit and section 12(1) has been correctly applied in this case.

Section 16 – the duty to provide advice and assistance

36. Section 16(1) of FOIA sets out a duty for a public authority to provide advice and assistance to anyone who has made, or is thinking of making, a request for information.

37. Where a public authority claims that section 12 of FOIA is engaged it should, where reasonable, provide advice and assistance to help the requestor refine the request so that it can be dealt with under the appropriate limit, in line with section 16 of FOIA.

38. The Commissioner notes that when responding to the request the MHRA asked the complainant which of the conditions listed they wanted it to provide evidence for. The complainant argued that if the conditions had all been met the data should be readily available and it would not be unreasonable to complete the request in full.

39. The Commissioner is satisfied the MHRA met its obligations under section 16 of FOIA as it suggested focusing the request on specific conditions.

Right of appeal

40. 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

41. 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.

42. 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 .....

Jill Hulley
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