Reference: IC-167627-X2Z0

Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 18 November 2022

Public Authority: Medicines and Healthcare products Regulatory Agency

Address: 10 South Colonnade
Canary Wharf
London
E14 4PU

Decision (including any steps ordered)

1. The complainant has requested all the data the MHRA relied on to approve the Pfizer, AstraZeneca and Moderna COVID-19 vaccines. The MHRA refused to comply with the request under section 14(1) of the FOIA.

2. The Commissioner's decision is that the MHRA has correctly applied the exemption and refused the request on the basis of section 14(1) of the FOIA.

Request and response

3. On 15 March 2022 the complainant made a request to the MHRA for the following information:

> "Under the FOIA act please could you supply me with all the data and information which the MHRA relied upon to give approval for the use of the Pfizer, AZ and Moderna covid-19 vaccines."

4. The MHRA responded on 5 April 2022 providing a link to the European Medicines Agency (EMA) clinical data website which it stated had the clinical data submitted for each of the authorised vaccines.

5. The complainant responded on the same date stating this was not what he asked for. The complainant asked for confirmation that the MHRA's decision to authorise use of the vaccines was solely based on the information provided in the link and that no other data or information was used at any time.

6. The MHRA responded further on 6 April 2022, explaining temporary authorisations were done through an expedited rolling review. Further explanations were given as to the different phases of clinical trials that each vaccine goes through. Information was provided on the Pfizer/BioNTech vaccine study and a link provided to the results published in the New England Journal of Medicine.

7. The complainant responded on 15 April 2022 pointing to a paragraph in the 6 April 2022 response that stated:

> "The temporary authorisations for use of the COVID-19 vaccines in the UK followed a rigorous scientific assessment of all the available evidence of quality, safety and effectiveness by the UK regulator, the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA expert scientists and clinicians reviewed data from laboratory pre-clinical studies, clinical trials, manufacturing and quality controls, product sampling and testing of the final vaccine, and also considered the conditions for its safe supply and distribution. The decision was made with advice from the Commission on Human Medicines (CHM)."

8. The complainant reiterated they wanted all the information and data used by the MHRA to approve use of vaccines in the same format it was used by the MHRA scientists and clinicians as referred to above.

9. The MHRA conducted an internal review and responded on 18 May 2022. The MHRA had considered the request was about safety data however, it now acknowledged the applicants had all submitted data to gain regulatory approval to support the quality of their product as well as details and data on non-clinical/lab-based tests. It advised this data is available in public assessment reports and provided a link but explained some information was redacted on the basis of section 43 (commercial interest) and 41(information provided in confidence) of the FOIA.

Scope of the case

10. During the course of the Commissioner's investigation the MHRA changed its position.

11. The Commissioner initially asked the MHRA questions to understand its use of the section 43 and 41 exemptions and to ascertain exactly what information was being withheld. Following discussions the MHRA amended its position and wrote to the complainant explaining there was a "vast quantity of data and documents what would fit within a request for all information on which the approval of the three COVID-19 vaccines was based".

12. The MHRA stated it now considered the burden on its resources to respond would be excessive and exemptions may apply to some of the information. The MHRA therefore asked the complainant to consider refining their request to avoid placing an oppressive burden on the MHRA.

13. The MHRA provided some detail on the content of the regulatory dossier so as to be able to provide a suggestion on how the request could be refined. The MHRA explained that the regulatory dossiers of vaccines and medicines are organised in a modular structure with modules from 1-5. The MHRA provided a link to a document[1] where a summary of each module could be found. The MHRA suggested this structure could be used to consider the individual documents or studies from the regulatory dossier that the complainant was most interested in.

14. The MHRA also suggested a possible refinement:

    "we provide a copy of the clinical and non-clinical overviews (summaries of the data submitted in modules 4 and 5) for one of the products concerned by the request. In a similar manner to the dossier structure provided above, these documents can then be used to identify specific clinical or non-clinical studies that might be of interest to you, and these can subsequently be requested through FOI, please note any documentation supplied to address an FOI request may be subject to redactions under FOIA. Also note, that the studies used to support the assessment are also detailed/summarised in the public assessment reports provided in our earlier correspondence with you."

15. The MHRA states that this suggested refinement was intended to guide the complainant toward the non-clinical and clinical data as the majority of the information on quality of medicines and vaccines would be

[1] Microsoft Word - CTD-introduction-rev-June-2004-clean final.doc (europa.eu)

commercially sensitive and unlikely to be disclosed under FOIA. The MHRA further explained it used the guidance in the EMA/HMA transparency document[2] when considering redactions. It explained this document itemised the dossier structure and marks information into three categories – commercially confidential, can be released, or where case-by-case approaches should be used. The MHRA indicated this document should be used as a guide for submitting a refined request because information marked as commercially confidential would be unlikely to be released i.e. the majority of module 3 (information on the quality of the vaccine).

16. The complainant considered the MHRAs updated position and responded that, as the MHRA had confirmed there was lots of data in scope of his request, they now wanted all of this to be made available. The complainant acknowledged that this may involve significant amounts of data but did not accept this would place an unfair and inappropriate burden on the MHRA or that the information should be exempt from disclosure.

17. As the complainant did not accept the suggested refinement of the request the MHRA maintained its position that to comply with the request in full would create an oppressive burden and the request was therefore refused under section 14 of the FOIA.

18. The scope of the Commissioner's investigation is therefore to consider whether the MHRA has correctly engaged section 14(1) to refuse the request.

Reasons for decision

19. Section 14(1) of FOIA allows a public authority to refuse to comply with a request if it is considered to be vexatious.

20. In the Commissioner's view, section 14(1) is designed to protect public authorities by allowing them to refuse any requests which have the potential to cause a disproportionate or unjustified level of disruption, irritation or distress. This will usually involve weighing the evidence about the impact on the authority and balancing this against the purpose and value of the request. This should be judged as objectively as possible; in other words, would a reasonable person think that the

[2] Microsoft Word - HMA_EMA_Guidance_Document_20120309_adopted_clean.doc

purpose and value are enough to justify the impact on the public authority.

21. In particular, the Commissioner accepts that there may be cases where a request could be considered to be vexatious because the amount of time required to review and prepare the information for disclosure would place a grossly oppressive burden on the public authority. This is the position adopted by the MHRA in this case.

22. The Commissioner believes that there is a high threshold for refusing a request on such grounds. This means that a public authority is most likely to have a viable case where:

    - The requester has asked for a substantial volume of information;
    - the authority has real concerns about potentially exempt information, which it will be able to substantiate if asked to do so by the Commissioner; and
    - any potentially exempt information cannot easily be isolated because it is scattered throughout the requested material.

23. The MHRA explained that the process of downloading the dossier for each vaccine would be a relatively straightforward task. It is the time needed to read through the dossiers and consider and make redactions that the MHRA argues would take weeks, if not months to complete as the request encompasses gigabytes of data.

24. The MHRA has stated that staff would firstly need to read the dossier in full for each of the three vaccines in order to identify where redactions need to be made. The dossiers would then need to be extracted, a process the MHRA describes as straightforward but not "time negative".

25. The MHRA explained it would need to seek the view of third parties and this would then require further resource to consider any proposals against transparency guidelines and FOI criteria. The MHRA argues that the material that may need to be redacted is dispersed unevenly throughout the dossier, for example personal information is present in many documents in terms of authors and clinical data needs to be carefully checked that identifiers of pseudo-identifiers of trial participants or patients are not present. The MHRA states extreme care must be taken to ensure no names of research organisation staff are included, specifically in the non-clinical portions of the dossier due to a risk from animal rights activists.

26. The MHRA advised the quality parts of the dossier also include a mix of information that can be released and information that should be withheld. By way of example, it stated that the heading in a table of

parameters could be disclosed but the acceptance criteria are likely to be commercially sensitive. Proposed redactions would require input from different assessment teams to understand if the information would be commercially sensitive.

27. In terms of redactions, the MHRA states these would have to be done manually using a mark-up tool in Adobe as they consider using an automated redaction tool to be risky as they can overlook misspelled words. Once the MHRA has made the manual redaction in Adobe it then has to make them irreversible which is done document by document. The MHRA expects almost all documents in each dossier to have a redaction of some sort.

The Commissioner's position

28. With regard to the three criteria set out above at paragraph 22, the Commissioner accepts that the first one is met. The information in the dossiers is clearly voluminous.

29. With regard to the second criterion, the Commissioner notes the exemptions that the MHRA has suggested would need to be considered in relation to information falling within the scope of the request. Taking into account the volume and range of information falling within the scope of the request the Commissioner is satisfied the MHRA's concerns that the requested information may contain potentially exempt information are legitimate ones. In reaching this finding the Commissioner is particularly persuaded by the concerns regarding personal data and the amount of data that may need to be redacted from each document. The Commissioner also accepts there would be information in the dossiers that would need to be considered to determine if it might be commercially prejudicial and where this relates to third party commercial interests there may be a need to consult with that party.

30. With regard to the third criterion, based on the MHRA's submissions the Commissioner is satisfied that the potentially exempt information cannot be easily isolated.

31. The HMA/EMA (Heads of Medicines Agency/European Medicines Agency) guidance referred to earlier is intended to assist bodies dealing with information requests on medicinal products, ultimately the decisions are the public authorities to make but it is clear this document is used to provided consistency and guidance.

32. From reviewing this documents it is clear there is a great deal of information that will need to be considered by the MHRA. For personal data alone it is suggested there will need to be separate considerations

for the personal data of experts, other staff, designated personnel, patients, clinical trial participants and other individuals. The MHRA will need to identify the personal data in each case and then determine which category it fits into before determining if this should be redacted or not.

33. For potentially commercially confidential information the HMA/EMA document suggests a number of types of information likely to be found in dossiers that may be commercially confidential and need to be considered by the MHRA for redaction.

34. The HMA/EMA documents then goes on to provide an example of Module 1-5 in a dossier and analyses this page by page to show the standard types of information and what may need to be considered on a case by case basis, what can be released as it is publicly available and what is either likely to be personal data or commercially confidential information. Form this it is clear that potentially exempt information cannot be easily isolated.

35. In respect of the time required to process the request, the Commissioner notes that the MHRA has not been particularly specific, instead noting that the information amounts to gigabytes and may take several weeks to consider.

36. The HMA/EMA documents provide some further clarification on this point. It provides an example Module 1-5 from a single dossier amounting to 33 pages. This example document only includes example data and headers for some categories so it is reasonable to assume that if it was populated with actual information the information could extend well beyond 33 pages for each dossier. The Commissioner is aware that there is a dossier for each of the vaccines, Pfizer, Moderna and AstraZeneca.

37. In the Commissioner's view the range of information in these documents combined with the volume of information and the complexity of it would not make responding to the request a quick task. There would be a significant volume of work in analysing the information in the dossiers, identifying what may possibly be exempt and seeking the opinions of those with sufficient knowledge/expertise of the information to make decisions and process the request.

38. The Commissioner is not minded to accept that this process would take months but it is not unreasonable to conclude that it could take a significant amount of time given the technical nature of much of the information and the volumes of information to consider. On this basis the Commissioner is satisfied that the MHRA has demonstrated that the

three criteria are met and that as a result complying with the request would place a grossly excessive burden on it.

39. The Commissioner has gone on to consider whether the purpose and value of the request are enough to justify the impact on the public authority.

40. The complainant pointed to the public interest in the products and there continued use under emergency use terms as well as the "ever growing incidents of serious adverse events", highlighting the need for all data to be available so it can be looked at by individuals and experts. The complainant argued only receiving select information would not achieve this.

41. They argued that taking into account the role of MHRA, nothing less than 100% transparency and openness should be expected and delivered. The complainant had suggested to the MHRA that the information could be released by manufacturer, starting with Pfizer and moving on to Moderna and AstraZeneca over a period of time – a suggestion the MHRA rejected as this would still involve the same amount of burden just spread out over a longer time period.

42. The complainant strongly argued that the information should be available for all the burden only exists because the MHRA did not make the information available at the time they received it. They point to the MHRA receiving funding by many organisations with financial interests in the vaccines and that the interests of these organisations should not be protected over the general public and their safety.

43. The MHRA stated it appreciated there is a heightened public interest in COVID-19 vaccines, however, it did not feel that the public interest outweighs the resource burden required to meet the request. In terms of transparency, the MHRA stated it had already devoted large amounts of time to creating resources that are in the public domain, primarily the Public Assessment Reports (PARS) which include data that were integral to the benefit risk of the vaccines at the time of approval, especially the clinical safety and efficacy data.

44. In the vast majority of cases, the MHRA's understanding is that the data included in the PARs, Summary of Product Characteristics (SmPCs) and other documentation such as that related to pharmacovigilance address the public interest surrounding the approval of the COVID19 vaccines.

45. The MHRA also pointed out the regulatory status of the COVID-19 vaccine had changed. The vaccines referred to in the request are no longer supplied under temporary authorisation legislation but are now supplied under conditional marketing authorisations. As such the MHRA

argued that responding to the request in full would not represent a good use of resource.

46. In terms of the need for independent review of the COVID-19 vaccine data that the complainant considered was necessary; the MHRA stated that it operates licensing procedures in conjunction with the advice and decisions of independent panels/expert groups. These groups are made up of experts from UK academic and medical institutions such as professors, researchers and consultants.

47. The Commissioner appreciates the complainant has made a case for why, in their view, there is a compelling interest in disclosure of the full information held by the MHRA. There is a particular public interest in information relating to COVID-19 vaccines, the authorisation process of them and the details of the vaccines themselves. The information in this case would certainly go some way to meeting that public interest although the Commissioner notes it is likely to be very technical and specialist in significant parts so may not be of broad interest or use to lay people. In addition to this, the MHRA has explained its licensing procedures require the input of a variety of experts so there are already assurances that any vaccines authorised for use have been considered by expert panels and therefore been appropriately scrutinised.

48. That being said, there is a clear purpose and value to the complainant's request and this should not be dismissed.

49. However, it is precisely because of the volume and complexity of information in the scope of the request that has led the Commissioner to accept that the burden placed on the MHRA in complying with it is a grossly oppressive one. In the Commissioner's opinion despite the clear value in the disclosure of this requested information, he does not accept that this is sufficient to justify placing such a burden on the MHRA and expect it to undertake a significant amount of time to process this request. This is particularly relevant as the MHRA did go to lengths to attempt to be of assistance in refining the request, providing significant detail on how the information is structured in the dossiers and what might be disclosable if the request was narrowed – suggestions that were all rejected.

50. As a result, the Commissioner has concluded that the MHRA were entitled to refuse to comply with the request on the basis of section 14(1) of FOIA.

Right of appeal

51. 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

52. 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.

53. 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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