Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **6 March 2023**

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

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

Decision

1. The complainant has submitted multiple requests for information to Medicines and Healthcare Products Regulatory Agency ("MHRA") about Pfizer drugs.

2. The Commissioner's decision is that MHRA has not demonstrated that complying with the request would impose a grossly oppressive burden and consequently it is not entitled to rely on section 14(1).

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

   • To respond to the request again, without relying upon section 14(1) of FOIA.

4. MHRA 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 FOIA and may be dealt with as a contempt of court.

Request and response

5. On 18, 19, and 21 February 2022, the complainant wrote to MHRA, and submitted 5 requests for information about Pfizer drugs which can be found in the annex below, highlighted in bold.

6. MHRA refused to provide the information requested in all 5 requests citing section 14(1) (vexatious request) of the FOIA as its basis for doing so.

Reasons for decision

7. This reasoning covers whether the MHRA is entitled to rely on section 14(1) of the FOIA to refuse to provide the requested information.

8. In their complaint to the Commisisoner, the complainant stated that they do not consider their request to be vexatious. The complainant considers MHRA's refusal to be a "deliberate attempt to withhold potentially critical material from the public domain". The complainant also believes MHRA could have been more helpful by prioritising the urgent requests to assist with their research into Pfizer Covid-19 vaccince "being deployed in schools".

9. The position of MHRA is that it considers the requests to be vexatious and is excessive and placed an unnecessary burden on it.

10. MHRA stated it almagated the 5 requests because they received them over a period of 5 days and the subject of the requests overlapped each other.

11. The Commissioner's guidance states that a request may be vexatious if complying with the request would place a grossly oppressive burden on a public authority's resources which outweighs any value or serious purpose the request may have.

12. MHRA failed to submit any arguments in favour of its position despite the Commissioner providing it ample time to do so when an extension of time was granted.

13. Therefore, MHRA failed to demonstrate that the requests would place a burden on its resources.

14. The Commissioner appreciates that the complainant has made a detailed case for why, in their view, there is a compelling interest in the disclosure of the requested information. For these reasons, the Commissioner accepts that the complainant's request does have a clear purpose and value.

15. The Commissioner accepts that there are 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. Due to the volume of

information in the scope of the request, and the fact that potentially sensitive information would be contained within the query results, the Commissioner acknowledges that compiling the requested information would require some care. However, in this case MHRA has not provided sufficient evidence to demonstrate that the burden in complying with the request will be a grossly oppressive one. The Commissioner expects an executive agency to absorb a higher level of disruption and cost to comply with a request than a small public authority such as a parish council.

16. The Commissioner's decision is that MHRA is not entitled to rely on section 14(1) of the FOIA to refuse to comply with the requests.

Right of appeal

17. 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

18. 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.

19. 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 .....

Catherine Fletcher
Team Manager
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF

Annex 1

Request dated 18 February 2022:

According to the MHRA's public assessment report of Pfizer's experimental drug BNT162b2, in commenting on lipid-related impurities, "No critical issues have been identified with respect to the lipids that would preclude the emergency use of the vaccine." [1]

Please address the below with respect to BNT162b2.

1. Provide all documentation in possession of the MHRA fully covering all lipid-related impurity issues. In particular, provide an exhaustive list of all (known) lipid-related impurity issues relating to cholesterol (with respect to Ph. Eur. or otherwise) and ALC-0159, ALC-0315 and DSPC, where the applicant has defined and/or provided the quality control standards for the impurity control strategy or otherwise. Include all such issues regardless of severity.

2. Now clarify the MHRA's sentence quoted verbatim above. In particular, you should confirm whether any "critical issues" were identified with respect to lipid impurity control prior to the public assessment report. Note: "critical issues" exist irrespective of whether the MHRA judge such an issue to "preclude emergency use of the vaccine."

Annex 2

Request dated 19 February 2022:

According to Table 4 in the EMA's EPAR on Pfizer's experimental drug BNT16b2, 311 individuals in the treatment group and 60 individuals in the placebo group "had other important protocol deviations on or prior to 7 days after Dose 2".

Relative to the Dose 1 all-available efficacy populations (21,768 in the treatment group and 21,783 in the placebo group), assuming that such 7-day "important protocol deviation" events occur randomly in the absence of statistical significance (i.e. assuming the null hypothesis), the probability of observing such "extreme" results in either the treatment or placebo group (i.e. the two-tailed p test) is 0, with a corresponding Z-score of -13.093796.

This observed phenomena is thus not the result of randomness. With this statistical analysis in mind, please disclose all documentation concerning "important protocol deviations" in possession of the MHRA. This should include all requests made by the MHRA to Pfizer for clarity on these

"important protocol deviations" and all of their responses, an exhaustive list of all 371 "important protocol deviations on or prior to 7 days after Dose 2".

Furthermore, you should provide documentary evidence on the MHRA's internal investigation into this statistical abnormality, assuming the MHRA conducted such an investigation. If, to the contrary, the MHRA has not yet investigated this, please outline why the MHRA believes it is justified to date to have not investigated such a statistical anomaly and, finally, further outline the MHRA's plans to investigate this matter in the future.

Annex 3

Request dated 21 February 2022:

According to the ingredients table in Section 3.2 of Pfizer's Safety Data Sheet (SDS) for BNT162b2, the weight of water for injection is proprietary [1]. In addition to this, according to Table 2 in Pfizer's Summary Basis for Regulatory Action (SBRA) and Pfizer's Table 3.2.P.1-1 [2, 3], the amount of water for injection in the pre-dilution vial is "as much as may suffice." According to Pfizer's SDS, "In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret." This raises critical suspicions concerning informed consent of this experimental product.

Furthermore, the bottom row of Pfizer's SBRA has had at least 3 distinct values since being first issued on 23 August 2021. Initially redacted as a trade secret [4], it subsequently suggested water for injection is present at an amount of 0.450ml [5], before being revised to show the amount as q.s. (as much as suffices) [6].

Disclose all internal documentation, including correspondence between the MHRA and Pfizer and between the MHRA and other medical regulators (FDA, EMA etc.) on both the weight of water for injection in BNT162b2 and changes to Table 2 of Pfizer's SBRA with the FDA. In addition to this, disclose all internal documentation in possession of the MHRA on these topics, including emails, minutes of meetings and memorandums.

Annex 4

Request dated 21 February 2022

Recently, both sodium hydroxide and hydrochloric acid have been added to the list of excipients in Section 6.1 of the SmPC for Pifzer's experimental drug for the purpose of pH-adjustment [1]. Neither excipient is listed in Table 2 of Pfizer's Summary Basis for Regulatory Action (SBRA) [2].

You are required to comment on this discrepancy and this recent change to the SmPC. In particular, you should now publicly clarify whether this change in the excipient list applies retrospectively or only from the date these two excipients were added to the SmPC.

Disclose all documentation in possession of the MHRA concerning the recent addition of both sodium hydroxide and hydrochloric acid as excipients.

Annex 5

Request dated 21 February 2022:

In Section 3.2 of Pfizer's Safety Data Sheet (SDS) for BNT162b2, substances PF-07305885 and PF-07302048 appear as separate ingredients [1]. According to Pfizer's Summary Basis for Regulatory Action (SBRA), SARS-CoV-2 spike glycoprotein mRNA (modRNA) has a per-vial quantity of 225 µg and is the active pharmaceutical ingredient (API) [2]. There is thus no obvious way therefore to map these two ingredients from the SDS to the SBRA.

You are required to clarify the distinction between PF-07305885 and PF-07302048. Disclose all documentation in possession of the MHRA concerning these two chemicals, including documentation on their respective exact definitions and the distinction between the two. Disclose all communication between the MHRA and Pfizer and between the MHRA and other medical regulators (FDA, EMA etc.) on these two ingredients.