Freedom of Information Act 2000 (FOIA)

Decision notice

Date: **10 July 2023**

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 requested information about the COVID-19 vaccine Vaxzevria. By the date of this notice Medicines and Healthcare Products Regulatory Agency (the MHRA) had not issued a substantive response to this request.

2. The Commissioner's decision is that the MHRA has breached section 10(1) of FOIA in that it failed to provide a valid response to the request within the statutory time frame of 20 working days.

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

    - the MHRA must provide a substantive response to the request in accordance with its obligations under FOIA.

4. The MHRA must take this step 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 4 February 2023, the complainant wrote to the MHRA and made two requests for information in the following terms:

> "You have defined a set of Conditions of Authorisation for Vaxzevria. I would be grateful if you could provide several of the plans/reports/data you now hold in satisfaction of those conditions.
>
> Specifically:
>
> 1. The final report for a non-clinical study to test in-vitro expression of the S protein of Vaxzevria to elucidate the possible mechanisms of platelet activation after vaccination and to identify the possible triggers. According to your web site (Conditions of Authorisation for Vaxzevria) this document was due publication on 31 July 2021
>
> 2. Submission of a plan in RMP, timelines and protocols to further characterise the thrombosis and thrombocytopenia syndrome associated to the vaccine and elucidate its mechanism, the MAH should conduct suitable clinical studies. These documents were due publication on 31 Aug and 30 Sep 2021
>
> 3. 6-month and validated follow-up immunogenicity data of the COV trials to evaluate antibody persistence. This data was due publication on 31 July 2021
>
> 4. Updated data from the COV002 study to further evaluate vaccine efficacy against transmission. Due 31 Jan 2022
>
> 5. Data on breakthrough cases to investigate potential correlate(s) of protection.
>
> 5a. This report was due publication on 31 July 2021; both the 27 January and 27 June 2022 updates of your web site page (Conditions of Authorisation for Vaxzevria) showed this publication date.
>
> 5b. Was this an error in reporting to the public or are you withholding the report? If it was an error and the MAH was authorised to delay publication for at least 11 months, please supply communications and/or minutes of a meeting showing when and how this decision was made."
>
> And

"I am requesting the information you hold on AZ Vaxzevria Trial D8111C00004 (UK) apparently referred to in the November 2020 EMA RMP v1 as "ESR 21-21121 [UK] Ph IV Enhanced Active Surveillance"

I note a change in Version 4 of the EMA RMP, dated December 2021, removing D8111C00004 (UK) (and D8111R0003(EU) and D8110R00001 (US)) "due to recruitment challenges for study D8111R00003 (EU)" This followed a decision to that effect by the CHMP in November 2021.

Though removed as 'requirements' in December 2021, by that date there should have been the following material in place:

- Study Design Concept (11 Dec 2020)
- Study Protocol (28 Jan 2021),
- First interim report Q3 2021.

Please provide copies of these documents as well as confirmation that the study began on 8 June 2021 and what organisation led the work.

Please confirm whether the trial was terminated and, if so, when. If the trial continued, please confirm what organisation leads the work, what results are (will be) available and when."

6. The MHRA merged these requests and acknowledged them on 7 February 2023 under one reference number. To date, a substantive response has not been issued.

Reasons for decision

7. Section 1(1) of FOIA states that:

> "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."

8. Section 10(1) of FOIA states that a public authority must respond to a request promptly and "not later than the twentieth working day following the date of receipt".

9. On 6 June 2023 the Commissioner wrote to the MHRA, reminding it of its responsibilities and asking it to provide a substantive response to the complainant's request within 10 working days.

10. Despite this intervention the MHRA has failed to respond to the complainant.

11. From the evidence provided to the Commissioner in this case, it is clear that the MHRA did not deal with the request for information in accordance with FOIA. The Commissioner finds that the MHRA has breached section 10(1) by failing to respond to the request within 20 working days and it is now required to respond to the request in accordance with FOIA.

Right of appeal

12. 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

13. 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.

14. 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 .....

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