Freedom of Information Act 2000 (FOIA)

Decision notice

Date: 3 August 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 SKYCovion. By the date of this notice Medicines and Healthcare products Regulatory Agency MHRA had not issued a substantive response to this request.

2. The Commissioner's decision is that 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 MHRA to take the following step to ensure compliance with the legislation.

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

4. 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 10 June 2023, the complainant wrote to MHRA and requested information in the following terms:

> "On 26 May 2023, SKYCovion, a COVID-19 vaccine developed by SK Chemicals, was authorised by the Medicines and Healthcare products Regulatory Agency (MHRA). This authorisation was based on advice received from the independent Commission on Human Medicines (CHM).
>
> I would be grateful if you could provide copies of the communications/documents/evidence considered as the basis for authorising SKYCovion.
>
> 1. Please provide the request sent to the CHM for advice on the safety, quality and efficacy of SKYCovion
>
> 2. Please provide the advice given to the MHRA by the CHM on the safety, quality and efficacy of SKYCovion
>
> 3. Please provide any advice received from the CHM on the impact of any safety issues on the balance of risks and benefits of SKYCovion
>
> 4. Please provide evidence of correlates of protection underpinning the decision to infer efficacy from immunobridging
>
> 5. Please provide any representations, reports or other evidence, other than from the CHM, considered by the MHRA in support of the authorisation of SKYCovion in respect of:
>
> a. the quality, safety and efficacy of SKYCovion
>
> b. the balance of benefit and risks
>
> c. measures to minimise risks, and optimise the benefit-risk balance, such as any new precautions or restrictions on use
>
> d. communications to health professionals and the public.
>
> e. measures to monitor impact/effectiveness of any additional risk minimisation.
>
> 6. What obligations have been defined in respect of the provision of further evidence?

7. Please provide documentary evidence of the MHRA's consideration of the rationale for authorising a vaccine about which:

a. Efficacy inferred by comparison of immune response with another vaccine rather than in a clinical trial

b. Interaction studies had not been conducted

c. Genotoxicity and carcinogenicity studies were not performed

d. There is no experience with use in pregnant women from clinical trials

8. Please provide the risk management plan for SKYCovion

In case you feel the scale of the evidence requested above qualifies for a Section 12 exemption, please address the information in the numbered order *as far as practicable*. Where information cannot be provided due to the scale of effort, please explain the issue."

6. MHRA acknowledged the request on 22 June 2023. 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 18 July 2023 the Commissioner wrote to 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 MHRA has failed to respond to the complainant.

11. From the evidence provided to the Commissioner in this case, it is clear that MHRA did not deal with the request for information in accordance with FOIA. The Commissioner finds that 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 .....

Roger Cawthorne
Senior Case Officer
Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF