

INTERNAL REVIEW OF MHRA'S HANDLING OF FOIA REQUESTSSUBMITTED VIA EMAIL
info@mhra.gov.uk

July 1, 2022

Re: Request for Internal Review of FOI 22/674 (IR#0751A-D)

Dear Sir or Madam:

This firm represents the Informed Consent Action Network (“**ICAN**”). On behalf of ICAN, on April 28, 2022, we submitted requests for records (“**FOIA Requests**”) from the files of the Medicines & Healthcare products Regulatory Agency (“**MHRA**”) pursuant to the Freedom of Information Act 2000 (“**FOIA**”). On May 5, 2022, the MHRA Customer Experience Centre responded to the FOIA Requests (“**Final Response**”). ICAN writes now to request an internal review of the handling of the FOIA Requests.

A. FOIA Request – FOI 22/674 (IR#0751A-D)

On April 28, 2022, ICAN submitted the following requests separately via email to the MHRA:

IR#0751A: (Exhibit 1.)**All documents the MHRA relied upon to approve the use of Pfizer's COVID-19 vaccine and/or Comirnaty.****IR#0751B: (Exhibit 2.)****All documents the MHRA relied upon to approve the use of Moderna's COVID-19 vaccine and/or Spikevax.****IR#0751C: (Exhibit 3.)****All documents the MHRA relied upon to approve the use of Janssen's COVID-19 vaccine and/or COVID-19 vaccine Ad26.COV2-S [recombinant].****IR#0751D: (Exhibit 4.)****All documents the MHRA relied upon to approve the use of AstraZeneca's COVID-19 vaccine and/or COVID-19 vaccine ChAdOx1 S [recombinant].**

B. MHRA's Final Response & Follow up Communications

On May 5, 2022, the MHRA issued a final response letter. The letter assigned all the requests FOI # 22/674 and stated in part,

Thank you for your emails of 29th April (6 in total) regarding the regulatory approval of the Covid vaccines. . . . The authorisation of the Pfizer/BioNTech, AstraZeneca and Moderna vaccines under Regulation 174 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 the 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), the government's independent expert scientific advisory body. Regarding the MHRA approval of the Pfizer/BioNTech and the Oxford/AstraZeneca COVID-19 vaccines, further information (including information for physicians and recipients of the vaccine, and Public Assessment Reports [PARs] for each vaccine) are available on the MHRA website. . . .

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date you receive this response and addressed to: info@mhra.gov.uk

(Exhibit 5.)

To resolve our client's dissatisfaction with the thoroughness of the Final Response, on May 10, 2022, we emailed MHRA Customer Services and stated,

Our client's request was for all documents relied upon for the regulatory approval of the COVID-19 vaccines, not just the documents that are publicly available.

To further clarify the scope of our client's request, in your letter you state, "[t]he MHRA expert scientists and clinicians reviewed data from the 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" – these are the documents and data our client is requesting.

(Exhibit 6.)

In response to our follow up email, on May 30, 2022, MHRA Customer Services responded stating in part,

If we were to process this request in its present state under FOIA, unfortunately, we would need to refuse it under Section 12 or 14.

Section 12 applies when the cost exceeds then limit [sic] of 24 hours to determine if the information is held, locate, retrieve, and extract the information.

A Section 14. refusal, can be used in situations where handling multiple requests or a single request, would lead to a grossly excessive burden being placed on the public body or institution. We expect that this burden would be incurred due to the need to read, consider, and apply redactions, to the vast array of regulatory material encompassed by the request.

However, in line with the ICO advice related to advice and assistance. [sic] We would like to suggest that your client considers an early refinement of their request before a formal refusal notice is issued. We do not wish to steer your client in a specific direction with regards to refinement, as this could be mis-interpreted. Therefore, we instead propose that your client reviews the public assessment reports (see, correspondence on 5 May 2022) and selects a certain study or concept which they find of particular interest. Then should they wish to, your client/s can lodge a refined request or requests. . . .

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

(Exhibit 6.)

On June 13, 2022, we followed the “ICO advice” recommended in the MHRA’s follow up email by refining one of our requests (IR#0751A) regarding Pfizer’s COVID-19 vaccine/Comirnaty . The refined request submitted to MHRA on June 13, 2022 states,

Our Refined Request

- 1. Any document that references Subject ID number: 12312982**
- 2. The full ingredient list of the vaccine**
- 3. All documents concerning site number 1085 (Ventavia Research Group)**
- 4. The dataset for ADC19EF**
- 5. All Reports of Efficacy and Safety Studies**
- 6. All Reports of Postmarketing Experience**
- 7. All periodic safety reports submitted by the sponsor to the MHRA**
- 8. All documents concerning Important Protocol Deviations (IPDs)**

Additionally, on June 17, 2022, we refined the other requests (IR#0751B, IR#0751C, and IR#0751D) and submitted them to MHRA. Those requests were refined as the following:

All safety-related documentation relied upon to approve the use of AstraZeneca's COVID-19 vaccine and/or COVID-19 vaccine ChAdOx1 S [recombinant], Janssen's COVID-19 vaccine and/or COVID-19 vaccine Ad26.COV2-S [recombinant], and Moderna's COVID-19 vaccine and/or Spikevax, including but not limited to:

- 1. Cumulative Analysis of Post-authorization Adverse Event Reports All Reports of Efficacy and Safety Studies**
- 2. Monthly Safety Reports**
- 3. Summary of Clinical Safety**
- 4. Nonclinical Overview**
- 5. Overview of Toxicity Testing Program**
- 6. Clinical Overview**
- 7. Overview of Safety**

(Exhibit 7.)

As of the date of this request for an internal review, we have not received a response from MHRA regarding our refined responses.

C. Argument

We submit this request for an internal review because our client was dissatisfied with the Final Response MHRA provided in its May 5, 2022 letter. Our client was dissatisfied for several reasons. First, ICAN believes the scope of the request was improperly interpreted and resulted in a production of documents that was incomplete. Second, before the agency narrowly interpreted

the request and provided an incomplete production, ICAN should have been notified to any foreseeable processing issues regarding its requests so it could have had an opportunity to modify them. Third, ICAN believes the consolidation of the requests was unjustified and resulted in the limitation of processing time each request is entitled to under FOIA. Finally, ICAN believes the scope of the requests wouldn't, when processed separately, justify the agency's refusal to process them under Sections 12 or 14.

D. Appellate Request

ICAN submits this request for an internal review because MHRA's letter dated May 5, 2022, required it to do so by July 4, 2022. However, ICAN would prefer that MHRA respond to and ultimately process our refined request for IR#0751A submitted on June 13, 2022, and the other refined requests (IR#0751B, IR#0751C, and IR#0751D) submitted to MHRA on June 17, 2022. Furthermore, MHRA's follow up email – sent May 30, 2022 – also provided an opportunity to request an internal review within two months of the receipt of that email. We hope that MHRA will forthwith review and approve our refined requests and agree to produce responsive records. ICAN reserves all rights until these issues have been properly resolved.

Thank you for your time and attention to this matter. If you require any additional information, please contact us at **(212) 532-1091** or through email at **foia@sirillp.com**.

Very truly yours,

/s/ Aaron Siri

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Enclosures