Medicines & Healthcare products
Regulatory Agency

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United Kingdom
gov.uk/mhra

[redacted]

10 May 2024

MHRA reference: FOI2024/00046

Dear [redacted]

Thank you for your information request of 20 April 2024. Your request is:

> *Module 1 of the AstraZeneca COVID-19 Vaccine Dossier*
>
> *All records concerning information "provided in the form of responses to questions" (see Attachment A) located in Module 1 of the dossier for the AstraZeneca COVID-19 vaccine and/or COVID-19 vaccine ChAdOx1 S [recombinant]*

We have been considering your request under the Freedom of Information Act 2000 (FOIA). To progress your request further, we need to ask you to provide us with more specific details about the information you are seeking.

We will explain where your request is not clear and provide advice about how you may clarify your request by describing the information you wish to receive.

Module 1 of the dossier contains the administrative information (consisting of the marketing authorisation application and appendices). It does not contain responses to questions. A list of the contents of Module 1 is provided in the below-linked document, pages 7 to 27, along with what information is releaseable and what is commercially sensitive. It should be noted that some information that is releaseable is already in the public domain.
https://www.hma.eu/fileadmin/dateien/HMA_joint/02-_HMA_Strategy_Annual_Reports/07-Transparency/2012_03_HMA_EMA_Guidance_20120309_ComPersInfo.pdf

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We will now close this request. In accordance with the Information Commissioner's guidance, when we receive this clarification from you, this will be dealt with as a new request.

The Information Commissioner's guidance can be found here:
https://cy.ico.org.uk/for-organisations/foi/freedom-of-information-and-environmental-information-regulations/interpreting-and-clarifying-requests/

Please contact us with any queries, quoting the reference number at the top of this email.

Yours sincerely

Healthcare, Quality and Access Group
Medicines and Healthcare products Regulatory Agency

Appeal rights
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 foi.request@mhra.gov.uk

If you remain dissatisfied with the outcome of the internal review, you have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of a request unless the requester has first asked us to conduct an internal review.

The Information Commissioner can be contacted through their online webform at:
https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/
Or in writing to: Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire, SK9 5AF