RE: FOI 23/998 - FOIA Request (IR#0982B)MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>

MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>
Fri 19/01/2024 17:21
To: [redacted]

FOI 23/998

Dear [redacted],

We are writing in response to your 4 requests of 19th December 2023, which we have logged together under the reference number FOI 23/998. These are:

- Request for *Module 2 of the AstraZeneca COVID-19 Vaccine Dossier (IR#0982D)*: letter dated 18 December 2023, submitted to the MHRA in an email dated 19 December 2023.

  > *All records concerning summaries of quality, clinical, and non**[1]**clinical information located in Module 2 of the dossier for the AstraZeneca COVID-19 vaccine and/or COVID-19 vaccine ChAdOx1 S [recombinant]*

- Request for *Module 1 of the AstraZeneca COVID-19 Vaccine Dossier (IR#0982C)*: letter dated 18 December 2023, submitted to the MHRA in an email dated 19 December 2023.

  > *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]*

- Request for *Modules 4 and 5 of the AstraZeneca COVID-19 Vaccine Dossier (IR#0982E)*: letter dated 18 December 2023, submitted to the MHRA in an email dated 19 December 2023.

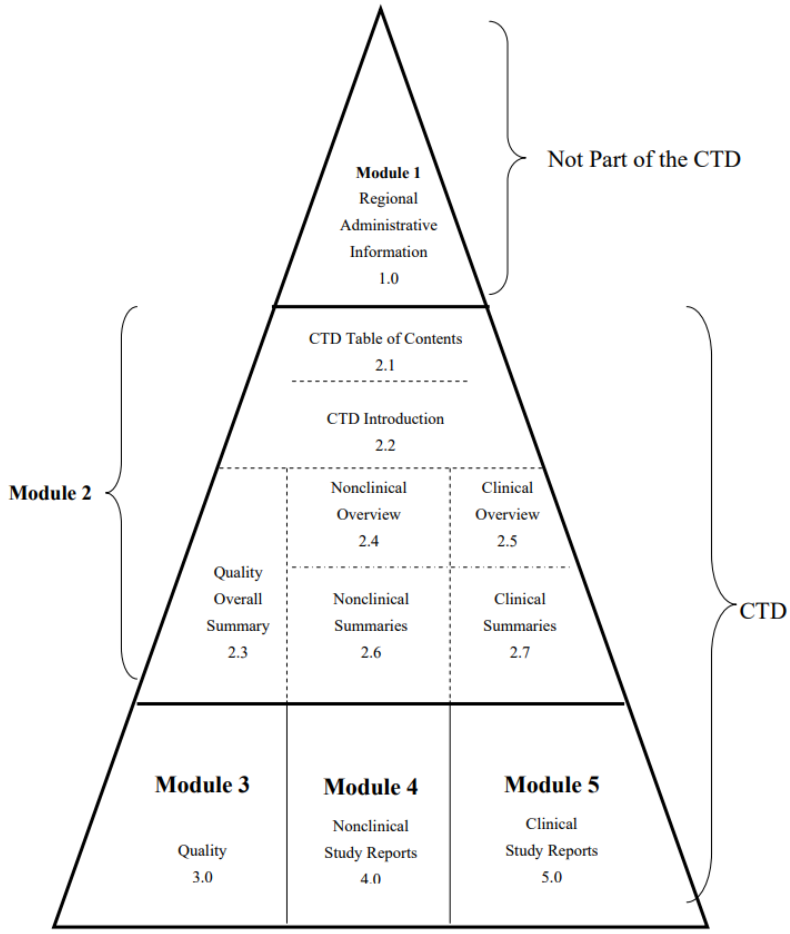
  > *All records concerning pre-clinical testing and clinical trials located in Modules 4 and 5 of the dossier for the AstraZeneca COVID-19 vaccine and/or COVID-19 vaccine ChAdOx1 S [recombinant]*

- Request for *Assessment Reports Concerning the AstraZeneca COVID-19 Vaccine Dossier (IR#0982B)*: letter dated 18th December 2023 in an email dated 19 December 2023.

  > *All "assessment reports" (see Attachment A) concerning the dossier for the AstraZeneca COVID-19 vaccine and/or COVID-19 vaccine ChAdOx1 S [recombinant].*

These 4 requests have been logged as one request, **FOI 23/998** as they all ask for similar and related information about the Astra-Zeneca COVID-19 Vaccine Dossier and were all made on the same day.

These requests ask for an extremely large amount of information. They followed the response issued to you for a previous request FOI 23/789, where we provided a diagram of the structure of a vaccine dossier:



In the response to FOI 23/789, we also gave advice on the types of information we would hold, as follows:

> *The majority of the pre-authorisation safety data will be in the form of information from clinical trials which are located in module 5 of the dossier, pre-clinical testing also covers aspects of safety (module 4). Module 3 which concentrates on the quality of the product is in a sense inseparable from safety; if the quality controls in place are appropriate a quality product is manufactured; thus contributing to safety. Module 2 includes overall summaries of quality, clinical, and non-clinical information.*
>
> *In addition to the above, new information can be provided in the form of responses to questions, and these would generally be located in the administrative module (module 1), however, new addenda and updated documents will also be included in the aforementioned modules. Module 6 includes post-marketing data, which can be present if a product has been marketed in another geographical location prior to authorisation in GB, NI, or the UK.*
>
> *In addition to the dossiers that MHRA hold for medicinal products described above, MHRA also hold assessment reports, these comment and assess the content of the dossier. In due course, a public assessment report is then generated based on the internal assessment report.*

We apologise that we did not perhaps make clear in that response that, if you were to submit multiple requests on the same day for entire Modules and assessments in respect of one vaccine dossier, these requests would be considered together, as they all ask for related information.

We should perhaps also have advised in the response to FOI 23/789 that, if you were to request the majority of the contents of one dossier in one request, or in a number of requests made on the same day, we would need to refuse these due to large amount of information which would then need to be considered for disclosure, and the disproportionate burden that this would cause.

We can explain that due to the voluminous size of the file packages within the modules you have requested, we have conducted estimates for previous requests which have indicated that the time required to read through the dossiers, to identify exempt information and to consider and then make redactions would take many weeks, as a dossier encompasses multiple gigabytes of data. When the time needed to review information to determine whether exemptions apply creates a disproportionate burden, section 14(1) may be applied to refuse the request.

The nature of this burden is clearly set out in a decision notice published by the information rights regulator, the Information Commissioner, which supported the MHRA application of section 14(1) in respect of a similar request for vaccine dossiers:

https://ico.org.uk/media/action-weve-taken/decision-notices/2022/4022928/ic-167627-x2z0.pdf

This decision notice concerns a request for three vaccine dossiers, however the principles of burden discussed in the decision notice are equally applicable to a request for one dossier. The Information Commissioner particularly noted that:

- "[…]*the Commissioner has concluded that the MHRA were entitled to refuse to comply with the request on the basis of section 14(1) of FOIA*."
- the ICO agrees that for considerations of the public interest under section 14(1), that interest was served by the inclusion of the main findings and outcomes of the non-clinical and clinical assessments in the Public Assessment Reports and other published information.
- The Information Commissioner agreed that potentially exempt information appears throughout a dossier and cannot be easily isolated. This indicates that the burden on resource necessary to trigger Section 14(1) can be met when detailed and careful redactions are required to voluminous material.
- The Information Commissioner was particularly concerned that different types of personal information are spread throughout the dossier, and that the MHRA would need to identify the personal data in each case and then determine which category it fits into before determining if it should be redacted or not.

We also note that in the published decision notice, no previous or later requests formed part of the decision that section 14(1) applied; in the case of your request, we have noted that the four requests submitted on 19 December 2023 followed a previous request for volumes of information which had been made within the last 60 consecutive working days, and which is currently the subject of an internal review. This is a further factor in the disproportionate burden as it may be considered in addition to the four requests of 19 December 2023. While we recognise the public interest in the disclosure of vaccine information (and this is discussed in some detail in the Information Commissioner's decision notice), this does not outweigh the significant burden that compliance would create in this instance as a result of the large scope of your requests.

We are providing advice and assistance to you in several ways. The ICO's decision notice records the value of the information published by the MHRA in meeting the public interest in the disclosure of information relating to the AstraZeneca COVID-19 Vaccine Dossier, and we refer you here to the published Public Assessment Report:

https://www.gov.uk/government/publications/regulatory-approval-of-covid-19-vaccine-astrazeneca/summary-of-the-public-assessment-report-par-for-vaxzevria

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1148800/CMA_UKPAR_COVID_19_Vaccine_AstraZeneca_PAR_PAR_update_Annex_I.pdf

We can further advise that the clinical data submitted for the EMA's assessment of the marketing authorisation concerning the AstraZeneca vaccine (and any subsequent clinical data submitted for variations to the marketing authorisation) are published by the European Medicines Agency (EMA). A link to their clinical repository is provided below:

https://clinicaldata.ema.europa.eu/web/cdp/home

We can also advise that the AZD1222 (ChAdOx1 nCoV-19) Covid-19 Vaccine in the UK and that used in the EU for is the same, therefore, the pivotal clinical trials and studies underpinning the submissions will be the same.

Finally, the main trials are already publicly available, for example, https://www.nejm.org/doi/full/10.1056/NEJMoa2105290.

We hope it will be helpful for you to review this published information prior to submitting a further and narrowed request, and that any narrowed request should be limited to one aspect of the information that you are most interested in.

We would recommend that to avoid your requests creating a cumulative burden, you submit only one request at a time. In this regard, we are aware that you already have an internal review ongoing in respect of a previous request (FOI 23/774) and that request also concerns large amounts of information. To avoid further aggregation or cumulative burden, we would suggest that you allow this internal review to be completed before submitting further new requests.

Once the review for FOI 23/774 is completed, we advise a narrowed request could be limited to the clinical and non-clinical overviews provided in the initial application for Vaxzevria, suspension for injection COVID-19 Vaccine (ChAdOx1 S [recombinant]) (PLGB 17901/0355), or alternatively the same in relation to the temporary authorisation of this vaccine under regulation R.174.

We hope this explanation of our refusal is useful for you.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask us to review our actions and decisions by writing to: info@mhra.gov.uk, and requesting an internal review.

Please note that your internal review request must be in a recordable format (email, letter, audio tape etc.), and that you have 40 working days upon receipt of this letter to ask for a review. We aim to provide a full response to your review request within 20 working days of its receipt. Please quote the reference number above in any future communications.

If you are not content 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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted online via an electronic form: 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,