FOI 23/620

Thank you for your refined request of 21 August 2023. We have provided our responses to each part of your request below. Each of your questions are included below for ease of reading.

Question 1. Please provide the final Clinical Study Reports following all subjects for 1 year post second dose for the randomised, controlled, COV005.

Response: We confirm that we hold the requested information.

However, we are aware of the clear intention for the EMA to publish this information on the Clinical Data Repository. We are therefore applying section 22(1) of the FOI; this information is exempt from disclosure because it is intended for future publication.

> Section 22
> (1) Information is exempt information if—
> (a) the information is held by the public authority with a view to its publication, by the authority or any other person, at some future date (whether determined or not),
> (b) the information was already held with a view to such publication at the time when the request for information was made, and
> (c) it is reasonable in all the circumstances that the information should be withheld from disclosure until the date referred to in paragraph (a).

Each of the three criteria must be met for section 22(1) to be engaged. The information is held by the MHRA with the settled expectation that the requested information for COV005 will be published at a future date; in this case, this expectation is based on the EMA's stated intent to publish clinical data for COVID-19 medicines in line with its exceptional transparency measures for COVID-19 and these publications are ongoing. This stated intent pre-dates your request.

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

https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-public-health-emergency-international-concern-2020-23/transparency-exceptional-measures-covid-19-medicines

The amount of data to be anonymised across the body of cross referenced papers and supporting material of which this paper forms a part means that the preparation for publication is expected to take at least some months. This work is progressing, but as the date of publication is to be determined by the EMA, we cannot advise further on the EMA's date for publication. As stated in section 22(1)(a), it is not necessary for the date of publication to be determined for section 22(1) to apply.

We believe it is reasonable in all the circumstances, fair, and in line with accepted practices, to withhold the information requested until its planned publication on the basis that:

- Responding to your request to provide the information ahead of this schedule would create a duplicated burden on our resource; this is because we would have to undertake the same detailed anonymisation exercise as the EMA is already conducting. Therefore, withholding the information at this time secures the best use of public resource.
- We should take a consistent approach to support scheduled publications of wider public benefit; in this case, there is a settled intent to publish the full body of material for these studies at a future date, rather than disclose parts of this in response to individual requests, and it is reasonable to maintain the schedule for this planned publication.

Public interest

We have considered the public interest within the process of engaging Section 22. A factor in favour is the general principle in transparency, to provide for earlier release of this particular information. We also understand there is a public interest in making the wider body available for public scrutiny. However, responding to individual requests for parts of the wider body of material on an ad hoc basis while a scheduled approach to wider publication is taking place, means that disclosure in this case gives only partial access to the wider material; we believe here that the strongest public interest lies in maintaining the schedule of publication intended by the EMA. Responding to individual requests also disrupts the existing approach to the process, creating a duplicated burden across two regulatory authorities, who would need to undertake the same process of review and consultation. This factor also favours maintaining the exemption.

We consider that these factors strongly support withholding the requested information at this time.

Question 2. Should this information be unavailable, please provide any communications or records of decisions whereby the MAH has been relieved of the obligation to deliver this information.

Response: The MAH has not been, and was not, relieved of the obligation to deliver the information you have requested to the MHRA; the Final Clinical Studies were provided by the MAH to the MHRA. Therefore, we do not hold the communications or records that you have asked for in this question.

Question 3. Please provide any communications between the MHRA, EMA and MAH concerning the first delay to publication of this information i.e. the slip to 31 December 2022.

Response: There are no communications between the MHRA, the EMA and the MAH concerning "*the first delay to publication of this information i.e. the slip to 31 December 2022*." We do not hold this information.

To explain, the date you have mentioned – 31 December 2022 is the due date for the submission of the data to the MHRA, it is not the date of publication for this information.

To explain, the date you have mentioned refers to the due date for the submission of data to the MHRA; it is not the date of publication for this information. This is shown in the extract from the CMA previously provided to you.

I. SPECIFIC OBLIGATION TO COMPLETE POST-AUTHORISATION MEASURES FOR THE CONDITIONAL MARKETING AUTHORISATION

This being a conditional marketing authorisation the Marketing Authorisation Holder shall complete, within the stated timeframe, the following measures:

Description	Due date
In order to ensure consistent product quality, the MAH should provide additional information on stability of the active substance and finished product (through the scheduled duration of 12 months) and review the finished product specifications following further manufacturing experience, where applicable.	28 February 2023
In order to confirm the efficacy and safety of COVID 19 Vaccine AstraZeneca, the MAH should submit the final Clinical Study Reports following all subjects for 1 year post second dose for the randomised, controlled, COV001, COV002, COV003 and COV005.	31 December 2022
In order to confirm the efficacy and safety of COVID 19 Vaccine AstraZeneca, the MAH should provide the final analysis from the pooled pivotal studies.	31 December 2022
In order to confirm the efficacy and safety of COVID 19 Vaccine AstraZeneca in the elderly and subjects with underlying disease, the MAH should submit the final clinical study report for study D8110C00001.	31 March 2024

In terms of the publication of these reports and data, these are not arranged by the MHRA. Arrangements are made by the relevant third parties with scientific journals or with the EMA if the data is to be included in their clinical data repository. The MHRA does not have a role in arranging these publications.

Yours sincerely

HQA FOI Team
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: info@mhra.gov.uk

Please remember to quote the reference number above in any future communications.

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 your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner’s Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF