Medicines & Healthcare products
Regulatory Agency

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[redacted]

29 May 2024

MHRA reference: FOI2024/00075

Dear [redacted]

Thank you for your information request, which we received on 29 April 2024. You asked:

> *"In relation to the Covid vaccines' Post Authorisation Safety Studies, please can you send me a copy of :*
> *- Moderna's P904 eu PASS Final Report (which was due to be published by 31 Dec 23)*
> *- Pfizer's C4591021 Interim Study Report 5 (which was due to be published by 31 Mar 24)"*

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

1) **Moderna P904 EU PASS Final Report**

After a search of our paper and electronic records in relevant and appropriate locations we have not been able to locate the information to address your request. In this instance the provision of the final report by the company has been delayed. The due date for the final report is now 30 September 2024 as shown in the EU Risk Management Plan version 8.2. Therefore, under Section 1(1) (a) of the FOIA we confirm that the information is not held.

2) **Pfizer C4591021 Interim Study Report 5**

We hold this information but consider that it is exempt under section 22(1) of the FOIA, as the information is intended for future publication.

In order to apply the exemption under Section 22(1), the FOIA states that the following points must be met:

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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).

We are satisfied all three parts of this exemption are met in this case. The information you asked for will be published in the fourth quarter of 2024 and the intent to publish predates your request for information.

Part (c) requires consideration of whether it is reasonable in all circumstances that the information is withheld from disclosure until the date of publication. When doing so, a public authority should consider whether or not it is sensible, in line with accepted practices and fair to all concerned.

In this case, we consider it this is reasonable because release of interim study results, prior to analysis and presentation in the final study report, may lead to misleading interpretations of the study findings.

Section 22 is a qualified exemption and therefore a public interest test must also be applied. This means that even if it is reasonable to withhold the information under section 22, the public interest in disclosure must be considered to determine if this outweighs the public interest in maintaining the exemption.

We have considered the public interest in disclosure or maintaining the exemption in this case. A factor in favour of disclosure 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 information available for public scrutiny.

We therefore consider that section 22(1) applies to the requested information at this time. 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 of this response; and can be addressed to this email address.

Yours sincerely,

FOI Team
Safety and Surveillance

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