



[REDACTED]
[REDACTED]

MHRA
10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

9 May 2024

Dear [REDACTED],

FOI 24/349

Thank you for your email of 10 April 2024, where, following the disclosure of information under FOI 24/209 and 23/908, you asked:

1. *Can you confirm that the only EWG meetings which took place regarding vaccines between Feb and April 2021 are the ones you have provided on the 4th Feb and 25th Feb? (ie nothing at in March 2021 or April 2021?)*
2. *I would like to put in a new FOI request. One of the documents you released to me is - "Covid-19 VBR EWG 25th Feb 2021". In this document, it says - "events of thrombocytopenia are being closely monitored and are discussed in a separate paper at this meeting". This sentence appears on page 4. I would like to see the paper mentioned and any other discussion about "thromboctopenia" by the EWG in Feb, March and April 2021.*

Response to Point 1

We can confirm that there were 14 COVID-19 Vaccine Benefit-Risk Expert Working Group (EWG) meetings conducted between 1 February and 30 April 2021, covering a range of COVID-19 vaccine safety topics. These meetings took place on:

- 4, 15 and 25 February
- 2, 9, 17, 18, 23 and 31 March
- 6, 12, 19, 23 and 26 April

In your request logged as FOI 24/209, you asked for any additional papers like the AstraZeneca vaccine safety review from 4 February, not any/all other EWG papers. So we provided the only other safety paper relating to AstraZeneca vaccine safety in the time frame, which was the document from 25 February.

Response to Point 2

The following documents were presented as papers or slide presentations to the EWG between 1 February and 30 April 2021, and discussed thrombocytopenia with any of the COVID-19 vaccines:



	EWG meeting date	Paper / slide presentation	Paper / Presentation Title
1	25-Feb-21	Paper	COVID-19 vaccines and the potential risk of immune thrombocytopenia
2	17-Mar-21	Paper	COVID-19 vaccines and risk of thromboembolic events with concurrent thrombocytopenia
3	23-Mar-21	Paper	Update on COVID-19 vaccines and risk of thromboembolic events with concurrent thrombocytopenia
4	31-Mar-21	Paper	Update on COVID-19 vaccines and risk of thromboembolic events with concurrent thrombocytopenia
5	31-Mar-21	Presentation	Thromboembolic events with thrombocytopenia: incidence rates and B/R calculations
6	06-Apr-21	Presentation	Update on COVID-19 AZ vaccine: Thromboembolic events with thrombocytopenia
7	12-Apr-21	Presentation	Update on COVID-19 vaccines and risk of thromboembolic events with concurrent thrombocytopenia
8	19-Apr-21	Presentation	Update on COVID-19 vaccines and risk of thromboembolic events with concurrent thrombocytopenia
9	23-Apr-21	Paper	Updated review of COVID-19 vaccines and the potential risk of thrombocytopenia events
10	26-Apr-21	Presentation	Update on COVID-19 vaccines and risk of thromboembolic events with concurrent thrombocytopenia

These 10 documents are being released to you with this response.

We are continuing to withhold some information in accordance with section 40(2), section 41(1) and section 43(2) of the FOI Act. We will explain these exemptions below.

Section 40(2) applies when personal data relates to individuals. This information is withheld as it falls under the exemption in sections 40(2) and 40(3)(a)(i) of the FOIA, which relates to the personal data of which the applicant is not the data subject. Section 40(2) of the FOIA provides that personal data relating to other persons is exempt information if disclosure would breach the Data Protection Act 1998 (DPA). We consider that disclosure of this information is likely to breach the first data protection principle in Schedule 1 to the DPA, which relates to the fair and lawful processing of personal data. Therefore, we have concluded that this information is exempt from disclosure under section 40(2) read in conjunction with section 40(3)(a)(i) of the FOIA.

Section 41(1) of the FOIA applies when information is provided to a public authority in confidence and states that:

41.—(1) Information is exempt information if —

(a) it was obtained by the public authority from any other person (including another public authority), and,

(b) the disclosure of the information to the public (otherwise than under this Act) by the public authority holding it would constitute a breach of confidence actionable by that or any other person.



The Information Commissioner (ICO) has provided extremely detailed guidance on section 41(1) and we have followed this guidance in this case.

<https://ico.org.uk/media/for-organisations/documents/1432163/information-provided-in-confidence-section-41.pdf>

We are withholding this information where this was obtained by the authority from other parties, including individuals, and the disclosure of this information would constitute a breach of confidence. The test of confidence has three parts; the information has the necessary 'quality of confidence' because it is more than trivial and not otherwise accessible, it was provided in circumstances importing an obligation of confidence, and disclosure would be an unauthorised use of the information which would be to the detriment of the party who provided the information. We therefore consider that disclosure would be an actionable breach with the likelihood that this action would succeed, and that Section 41(1) applies.

S43(2) applies where disclosure of the information would, or would be likely to, prejudice the commercial interests of any legal person (an individual, a company, the public authority itself or any other legal entity). This is a prejudice-based exemption, which means that information is exempt if its disclosure under FOIA if disclosure would, or would be likely to, prejudice the commercial interests of any legal person.

For information to be exempt from disclosure under section 43(2), the disclosure of the information would, or would be likely to, prejudice or harm commercial interests of an individual, a company, the public authority or any other legal entity. This is known as 'the prejudice test'. The test in this case relates closely to the 'detriment' mentioned above in respect of section 41(1), where third parties have provided information to the MHRA under confidentiality agreements.

S43(2) is a qualified exemption and requires consideration of the public interest.

In favour of publishing, we consider that there is a general public benefit where releasing the information demonstrates openness and transparency, and where this could contribute to public debate. However, this must be balanced against the greater public interest in ensuring that any such disclosure does not cause prejudice to a third-party.

In response to part b) of your request, minutes of the Expert Working Group on Covid-19 Vaccine Benefit Risk will be published in the future, subject to redaction of commercially sensitive information and that which was provided in confidence under the above exemptions, and thus provision of the minutes is considered exempt under Section 22 of the FOI Act. Section 22 of the Act allows public authorities to refuse requests where the authority intends to publish the information at a future and states that:

"Information is exempt if, at the time when the public authority receives a request for it:
(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 it will be published at a future date. We believe it is



reasonable in all the circumstances, fair, and in line with accepted practices, to withhold the information requested ahead of the wider schedule of publication.

As Section 22 is a qualified exemption, we have considered whether the public interest in maintaining the exemption is greater than public interest in disclosing the requested information.

We appreciate that there is a strong public interest in disclosure of information from the minutes of the COVID-19 VBR EWG. 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. However, responding to individual requests on an ad hoc basis while the information requested forms part of the scheduled approach to wider publication, creates an additional burden for staff and impacts on the existing approach to the process. This factor strongly favours maintaining the exemption. We consider it is the right decision to manage the availability of the information by planning its wider publication. It is also the case that the MHRA published regular updates of summaries of safety assessments in the Coronavirus summary of ADR reporting from February 2021 to March 2023, covering much of the period of the primary vaccination programme and several booster programmes. Therefore, on this occasion, we consider that the greatest public interests lies in maintain this agreed schedule of publication, and the public interest therefore favours maintaining the section 22 exemption at this time.

I hope this information is helpful.

Yours sincerely,
FOI Team,

The MHRA information supplied in response to your request is subject to Crown copyright. The FOIA only entitles you to access to MHRA information.

For information on the reproduction or re-use of MHRA information, please visit

<https://www.gov.uk/government/publications/reproduce-or-re-use-mhra-information/reproduce-or-re-use-mhra-information>

If you have a query about this email, please contact us.

If you are unhappy with our decision, you may ask for it to be reviewed. That review will be undertaken by a senior member of the agency who has not previously been involved in your request. If you wish to pursue that option, please write to the Communications Directorate, 4-T, Medicines and Healthcare products Regulatory Agency (via this email address). After that, if you remain dissatisfied, you may ask the Information Commissioner at:

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

Copyright notice

The information supplied in response to your request is the copyright of MHRA and/or a third party or parties and has been supplied for your personal use only. You may not sell, resell or