Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

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Dear [redacted]

FOI 23/782

Thank you for your email of 17 October 2023, where following our response to FOI 23/661 concerning information relating to blood clots with the AstraZeneca COVID-19 vaccine, you requested the following under the Freedom of Information Act, in relation to this safety issue:

a. *The assessment reports and presentations the MHRA provided to the Commission on Human Medicines and its Expert Working Group on COVID-19 Vaccine Benefit Risk from the end of February 2021 up to 6 April 2021*

b. *The minutes of the Expert Working Group on Covid-19 Vaccine Benefit Risk from 1st January 2021 up to 31st July 2021*

We can confirm that we hold the information requested. We responded on 14 November 2023 to advise that we had identified that the information requested engages section 43 and section 22 of the FOI Act, and as explained, these are qualified exemptions allowing further time (up to 20 working days) to consider whether the public interest in releasing the information is outweighed by the public interest in maintaining the exemption (the "public interest test"). Thank you for your patience while we have made these considerations; we can advise that where the public interest favours disclosure, we are now providing this information,

In response to a), please find attached the assessment reports and presentations MHRA provided to the Commission on Human Medicines and its Expert Working Group on COVID-19 Vaccine Benefit Risk (VBR EWG) from the end of February 2021 up to 6 April 2021. These are listed here:

Document	Meeting presented at
1 COVID-19 vaccines and the potential risk of immune thrombocytopenia VBR EWG redacted	25 February 2021 VBR EWG
2 COVID-19 vaccines – thromboembolic events associated with thrombocytopenia VBR EWG 17 Mar 21 redacted (paper)	17 March 2021 VBR EWG

3 COVID-19 vaccines – 23 Mar update thromboembolic events associated with thrombocytopenia redacted (paper)	23 March 2021 VBR EWG and 27 March 2021 CHM
4 COVID-19 vaccines CHM TE with thrombocytopenia 27 Mar redacted (slides)	27 March 2021 CHM
5 CHM EWG 31 Mar 21 – Further steps thromboembolic events associated with thrombocytopenia redacted (paper)	31 March 2021 EWG and 1 April CHM
6 COVID-19 vaccines EWG 31 Mar TE with thrombocytopenia data lock 29 Mar (slides)	31 March 2021 EWG and 1 April CHM
7 COVID-19 vaccines CHM 4 Apr TE with thrombocytopenia data lock 31 Mar (slides)	4 April 2021 CHM
8 COVID-19 vaccines VBR EWG 6 April 2021 TE with thrombocytopenia (slides)	6 April 2021 EWG and CHM

We are continuing to withhold some information in accordance with section 40(2), section 41(1) and section 43(2) if 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#:~:text=Section%2041%20sets%20out%20an%20exemption%20from%20the,its%20disclosure%20would%20constitute%20a%20breach%20of%20confidence.

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,