Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA
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Canary Wharf
London
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United Kingdom

www.gov.uk/mhra

14 December 2023

Dear [redacted]

FOI 23/697

Thank you for your email of 11 September 2023, [redacted] here you requested disclosure of:

- "Reports made to JCVI between 18 March 2021 and 7 April 2021 regarding low platelets and blood clots"
- "Communication with CHM and EWG including discussions with world wide haematologists"

We would like to apologise for the delay in responding to your request.

We can confirm that we hold some of the information requested.

Thank you for your patience while we have considered your request. While certain exemptions apply to parts of the information, and we will explain these below, we can advise that where the public interest favours disclosure, we are now providing this information.

Information provided

We will first explain the information we hold that is relevant to your request.

The MHRA review of blood clots occurring with thrombocytopenia was made up of numerous assessment reports and presentations, both of which contain a range of data including from Yellow Card reports of suspected adverse reactions, vaccine exposure, and incidence rates for medical events. These were presented to the Commission on Human Medicines (CHM), the CHM's COVID-19 vaccine benefit-risk Expect Working Group (COVID-19 VBR EWG) and the Joint Committee on Vaccination and Immunisation (JCVI) between March and April 2021.

We are providing these documents, subject to the exemptions described below.

The JCVI is an advisory body to UK health departments on immunisation. There is a main JCVI committee and various subcomittees which focus on specific areas of infectious disease. From

September 2020 to July 2021 a COVID-19 subcomittee met on a regular basis This was then replaced with a JCVI COVID-19 main committee meeting.The MHRA is often invited as an observer to JCVI committee meetings and was also invited to observe the COVID-19 meetings and on request, provide safety updates in relation to the COVID-19 vaccines.

It is important to note that as an observer, MHRA did not advise the JCVI, and safety updates were not presented at every meeting. Details of the safety information MHRA provided to JCVI concerning COVID-19 vaccine AstraZeneca and bood clots with low platelets can be found in the JCVI minutes here: COVID-19 Sub-committee | Powered by Box
COVID-19 main committee meeting minutes | Powered by Box

We have identified that this safety issue was discussed at the following meetings of the CHM, VBR EWG and JCVI between 18 March 2021 and 7 April 2021 and the associated documents which were used as a basis for presentation and discusson at these meetings:

Document	**Meeting presented/discussed at**
A COVID-19 vaccines – thromboembolic events associated with thrombocytopenia VBR EWG 17 Mar 21 redacted (paper)	JCVI 18 March 2021 (also presented at 17 Mar VBR EWG)
B COVID-19 vaccines – 23 Mar update thromboembolic events associated with thrombocytopenia redacted (paper)	23 March 2021 VBR EWG, 27 March 2021 CHM, 25 March JCVI COVID-1 subcommittee
B1 Proforma – thrombosis thrombocytopenia	23 March 2021 VBR EWG and 27 March 2021 CHM
C1 CHM EWG 31 Mar 21 – Further steps thromboembolic events associated with thrombocytopenia redacted (paper)	31 March 2021 VBR EWG and 1 April CHM
C2 COVID-19 vaccines EWG 31 Mar TE with thrombocytopenia data lock 29 Mar (slides)	31 March 2021 VBR EWG, 1 April CHM, 1 April JCVI COVID-19 subcommittee
D COVID-19 vaccines CHM 4 Apr TE with thrombocytopenia data lock 31 Mar (slides	4 April 2021 CHM
E COVID-19 vaccines VBR EWG 6 April 2021 TE with thrombocytopenia (slides)	6 April 2021 VBR EWG, 6 April CHM, 6 April JCVI COVID-19 main meeting

These documents are provided with this letter.

We have interpreted the part your request for ‘discussions with worldwide haematologists’, as seeking the formal output of these discussions. We can explain that haematologists attended some of the CHM EWG meetings and MHRA consulted with haematologists to agree a case definition for the syndrome and a proforma for following possible reports of thrombosis with thrombocytopenia. We have provided a copy of this proforma.

Exemptions applied to certain information

In regard to the documents provided, 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. information-provided-in-confidence-section-41.pdf (ico.org.uk)

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.

We hope this information we have provided is helpful.

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.

Medicines & Healthcare products Regulatory Agency

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Yours sincerely,

FOI Team,

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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