Medicines & Healthcare products
Regulatory Agency

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Canary Wharf
London
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United Kingdom
**gov.uk/mhra**

[redacted]

11 July 2023

FOI 23/416

Dear [redacted]

Thank you for your information request, dated 13 June 2023, where you asked for a copy of all minutes of meetings of the MHRA and any of its subcommittees which discussed the interim and/ or the final report for “A post-authorization safety study (PASS) to evaluate the paternal exposure to valproate and the risk of neurodevelopmental disorders including autism spectrum disorders as well as congenital abnormalities in offspring - a population-based retrospective study”, reference EUPAS34201.

Unfortunately, the information is exempt from release under sections:

Section 43 – Commercial interests: information where disclosure would be likely to prejudice the commercial interests of any person, including third parties or the public authority that holds the information. Section 43 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there is a general public benefit from better understanding the safety of valproate. However, we consider that the public interest will be better served by not releasing the information as it relates to an ongoing regulatory procedure which is subject to a full reanalysis and is unlikely to be completed before March 2024. Releasing the information would also prejudice the Agency’s commercial interests in this case and in future. As a market regulator, it is vital that the Agency can freely engage in dialogue with organisations about commercial activities.

Section 22 – Information intended for future publication: the information you have requested is due to be published on completion of the regulatory procedure which is anticipated to be March 2024. Section 22 is a qualified exemption, which means that we have considered whether the public interest in releasing the information is

outweighed by the public interest in not giving the information. In favour of disclosure, we consider that there is a general public benefit from clear evidence based information on the safety of medicines such as valproate. However, we consider that the public interest will be better served by not releasing the information at this time as this procedure is subject to a full reanalysis and the results and consequential recommendation may change based on the data.

If you disagree with how we have interpreted the Freedom of Information Act 2000 with regards to your request, you can ask for the decision to be reviewed. The review will be carried out by a senior member of the Agency who was not involved with the original decision.

If you have a query about the information provided, please reply to this email.

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 were to remain dissatisfied with the outcome of the internal review, you would 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

Yours sincerely,
**Safety & Surveillance**