Medicines & Healthcare products
Regulatory Agency

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom
gov.uk/mhra

[redacted]

11 July 2023

FOI 23/415

Dear [redacted]

Thank you for your information request, dated 13 June 2023, where you asked for a copy of all correspondence and/ or emails with the European Medicines Agency which discusses either 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 section:

Section 27 – International relations: we consider that disclosure of this information is likely to damage the MHRA’s relationship with a regulator from another country, and thus could damage the UK’s interests abroad. Section 27 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 in understanding the safety of valproate. However, we consider that the public interest will be better served by not releasing the information as the MHRA’s correspondence with the European Medicines Agency relates to an ongoing regulatory procedure which is subject to a full reanalysis and is unlikely to be completed before March 2024.

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.

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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