Medicines & Healthcare products
Regulatory Agency

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

[redacted]

15 April 2026

MHRA reference: **FOI2026/00181**

Dear [redacted]

Thank you for your information request, which we received on 18 February 2026. You asked for:

> *"I am requesting access to original regulatory documents created, reviewed, or held by the MHRA or its predecessor bodies, including the Committee on Safety of Medicines (CSM), relating to teratogenicity studies conducted or assessed in 1972.*
> *Information requested*
> 1. *Rat study – sodium valproate vs phenytoin*
>   *Please provide:*
>   - *The complete 1972 paper/report produced by the CSM Sub-Committee on Toxicity and Clinical Trials concerning rat studies comparing sodium valproate and phenytoin, beginning at pages 0/1 and continuing in full, including:*
>   - *All pages without omission*
>   - *Tables, figures, appendices, and statistical analyses*
>   - *Marginal notes, annotations, or internal commentary*
>   - *Any accompanying covering papers, briefing notes, or submissions considered alongside the study*
> 2. *Rabbit teratogenicity study*
>   *Please also provide:*
>   - *The full rabbit teratogenicity study report referred to in the same regulatory context, including:*
>   - *Complete methodology and results*
>   - *Any comparative assessment involving sodium valproate and/or phenytoin*
>   - *Any internal evaluations, conclusions, or regulatory commentary generated by or for the CSM or its sub-committees*

Clarifications to prevent misinterpretation

- *This request is for primary source documents, not summaries, digests, or retrospective reviews.*
- *The age of the documents (circa 1972) strongly suggests that:*
  - *Commercial confidentiality exemptions are unlikely to apply, and*
  - *Any remaining personal data concerns can be addressed via proportionate redaction.*

If redactions are applied, please:

- *Cite the specific FOIA exemption relied upon for each redaction, and*
- *Provide the public interest test reasoning where applicable.*

Format and time limits
I request the information in electronic format (PDF or scanned copies).”

We have dealt with your request under the Freedom of Information Act 2000 (FOIA).

In response to your request, we are providing the following documents:

- **22 June 1972 Committee on Safety of Medicines (CSM) minutes**
- **Report for the teratogenicity studies in the Rabbit & Rat.**

Please note that some redactions have been applied to these documents under the Section 40(2) (S40 – Personal information), Section 41(1) (S41 – Information provided in confidence) and Section 43(2) (S43 – Commercial interests) of the FOIA.

We will explain these exemptions below.

Section 40:
(2) Information is exempt information if it contains elements of personal data, the disclosure of which would be unfair in that it would breach the first principle of the Data Protection Act which says that information must be processed fairly and lawfully.

Section 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.

Section 43:
(2) Information is exempt information if its disclosure under this Act would, or would be likely to, prejudice the commercial interests of any person (including the public authority holding it).

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Section 43 is a qualified exemption and requires that we consider the public interest.

Public interest test
Section 17(3) of the Act requires us to conduct a Public Interest Test (PIT) when applying of a qualified exemption. In applying this exemption, we are required to consider whether, in all the circumstances of the case, the public interest in withholding the information outweighs the public interest in releasing the information held. The 'public interest' is not the same as what interests the public. In carrying out a PIT, we consider the greater good or benefit to the community as a whole in withholding. The 'right to know' must be balanced against the need to enable effective procedural governance and to serve the best interests of the public. The FOI Act is 'applicant blind'. This means that we cannot, and do not, ask about the motives of anyone who asks for information. In providing a response to one person, we are expressing a willingness to provide the same response to anyone.

Considerations in favour of releasing the information
To release all information available in these documents would be of benefit in general to show transparency in MHRA's day-to-day work for the public to see the overall data supporting the approval of medicinal products.

Considerations in favour of withholding the information
Details contained in the CSM minutes includes discussion on other product licences which is outside the scope of this request. The information contained in the teratogenic study report is commercially sensitive information that has been provided to MHRA in confidence. Additional information on the bibliographic references has been redacted.

On balance we are satisfied that, in this instance, the public interest in applying the exemption outweighs the public interest in disclosure.

This concludes our response to your request.

If you have any queries about this letter, please contact us quoting the reference number above.

Yours sincerely,

MHRA Central Freedom of Information Team
Medicines & Healthcare products Regulatory Agency

Your right to complain under the Freedom of Information Act

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If you are not happy with this response you may request an internal review by e-mailing foi.request@mhra.gov.uk or by writing to: MHRA Central Freedom of Information Team, 10 South, Colonnade, Canary Wharf, London, E14 4PU

Any request for an internal review must be received by us within 40 working days of the date of this letter. Please note we are not obliged to provide a review if it is requested after more than 40 working days.

If you are not content with the outcome of the internal review, you may apply directly to the Information Commissioner's Office for a decision. Generally, the Commissioner cannot make a decision unless you have exhausted our own complaints procedure. The Information Commissioner can be contacted at: The Information Commissioner's Office, Wycliffe House, Water Lane, Wilmslow, Cheshire SK9 5AF.
Website: ICO FOI and EIR complaints or telephone 0303 123 1113.

Re-use of our information
The MHRA information supplied in response to your request is subject to Crown copyright. Information created by the MHRA which is disclosed under the Freedom of Information Act is made available for re-use under the Open Government Licence (OGL) v3.0, except where this is otherwise stated. There are some restrictions on re-use under the OGL, and these can be viewed here:
https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/