



Medicines & Healthcare products
Regulatory Agency

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[MHRA Website](https://www.mhra.gov.uk)

Our Ref: **FOI2026/00940**

21 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (FoI) request received on 23 August. You wrote:

Please provide recorded information held by the MHRA concerning the development of the strengthened valproate safety measures announced on 28 November 2023 and introduced from January 2024.

I am seeking to understand the recorded chronology by which relevant safety evidence was identified, assessed, escalated and translated into regulatory action.

Please provide:

- 1 *Any chronology, timeline or equivalent document prepared for, or used during, the MHRA/Commission on Human Medicines review of valproate safety in 2022 which records when significant safety evidence or signals were first received, identified or escalated, including in relation to:*
 - * *reproductive risks*
 - * *risks associated with exposure during pregnancy*
 - * *impaired fertility or reproductive effects in male patients*
 - * *emerging evidence concerning risks associated with paternal exposure*
 - * *continued prescribing notwithstanding previous safety measures.*
- 2 *The earliest internal briefing, assessment, paper or recommendation from the 2021-2023 period which considered materially strengthening the existing regulatory restrictions on valproate.*
- 3 *Copies of papers, minutes, decision records or recommendations from the Commission on Human Medicines and/or its relevant expert or implementation working groups during 2022 and 2023 which considered:*
 - * *whether further restrictions on valproate prescribing were required*
 - * *the options available*
 - * *the proposed restriction on initiation in patients under 55 years of age*
 - * *the requirement for two specialists independently to consider and document whether valproate should be initiated*
 - * *the proposed timetable for implementation*

4 Recorded information setting out the reasons for the timing of the strengthened regulatory measures, including any recorded consideration of:

- * whether action should have been taken earlier
- * whether stronger or weaker restrictions should be introduced
- * advantages, disadvantages or risks associated with alternative regulatory options
- * reasons for adopting the measures ultimately announced

5 The final decision or approval record authorising the regulatory measures announced on 28 November 2023 and implemented from January 2024.

This request is for recorded information only.

To assist in keeping the request within the appropriate cost limit, I am not requesting individual Yellow Card reports, patient-level information, routine administrative correspondence or duplicate copies of documents.

Where a document is already publicly available, I am content for the MHRA to identify it by title and link. However, the request includes any underlying non-public paper, minute, briefing, recommendation or decision record which is not contained in the published material.

If information within a document is exempt, I should be grateful if the exempt material could be redacted and the remainder disclosed with the exemption relied upon identified.

MHRA Response

We can confirm that the Agency holds this information. However, the information associated with points 1 to 4 is exempt under Section 21(1) of the Freedom of Information Act because the information is reasonably accessible to you, as it is already in the public domain.

You can find the information you seek in relation to points 1 to 4 within a public assessment report published at [Valproate: review of safety data and expert advice on management of risks - GOV.UK](#) and also within the Independent Medicines and Medical Devices Safety review report available at [the Independent Medicines and Medical Devices safety Review - Oral hearings](#). Annex C of the report contains the timeline of key events for sodium valproate regulation at [Annex-C-Valproate-timeline.pdf](#).

It is not clear what is being asked in point 5. A National Patient Safety Alert (NPSA) communicated the regulatory decision in November 2023 and requested implementation plans to be in place by the end of January 2024, this can be found at [National Patient Safety Alert: Valproate: organisations to prepare for new regulatory measures for oversight of prescribing to new patients and existing female patients \(NatPSA/2023/013/MHRA\) - GOV.UK](#). The MHRA does not hold the responses to the NatPSA.

The regulatory position was finalised with the approval of variations for each marketing authorisation holder of valproate containing medicines. The MHRA holds grant letters for each variation, however, the updated product information and updated additional risk minimisation measures (aRMMs) are available in the public domain on platforms such as the electronic medicines compendium (www.medicines.org)

Although the MHRA's website does not currently publish the aRMMs, the latest versions of the product information for each valproate containing medicine are available here: [MHRA Products | Home](#)

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

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

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<https://www.nationalarchives.gov.uk/doc/open-government-licence/version/3/>