Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00178**

15 April 2026

Dear [redacted]

Thank you for your Freedom of Information (FOI) request received on 18 February 2026. You wrote:

"MHRA's Commitments to Transparency on Teratogenicity
Please provide explicit information on the MHRA's policies, standards, and current or planned commitments in the following areas:

1.1 Regulatory Communication of Teratogenic Risks
- *How the MHRA identifies, assesses, and communicates teratogenic risks associated with medicines.*
- *Whether and how risk assessments of potential teratogenic effects (including pre-clinical and clinical evidence) are communicated to healthcare professionals, patients, and the public, including timelines.*

1.2 Publication of Safety Information
- *How and when the MHRA publishes safety signals and assessments related to teratogenicity (e.g., emerging evidence from post-marketing surveillance, safety reviews).*
- *What public registries, safety update reports, or risk communications the MHRA uses to ensure this information is accessible.*

1.3 Evidence Summaries and Decision Rationales
- *Whether MHRA publishes plain-language summaries or detailed rationales explaining how decisions involving teratogenic risk were reached (e.g., product labeling changes, contraindications, pregnancy warnings).*
- *If such summaries exist, the timelines within which they are made available following decision points.*

1.4 Patient and Public Engagement
- *How the MHRA engages with patients, advocacy groups, health professionals, and the public to inform them about the potential teratogenic risks of medicines.*
- *Whether there are mechanisms for patient feedback or involvement in regulatory communications specific to teratogenic risk.*
- *How does the MHRA choose members of any teratogenic stakeholder groups within the MHRA*

1.5 Confidentiality vs Public Interest
- *How the MHRA balances commercial confidentiality with the public interest in disclosing teratogenic risk data.*

- *The criteria used to decide when safety data, trial results, or risk-related evidence is withheld or published.*

2 *Transparency Obligations Imposed on Pharmaceutical Companies Related to Teratogenicity*

Please clarify what specific transparency requirements pharmaceutical companies must fulfil when interacting with the MHRA, particularly with respect to teratogenicity evidence, including but not limited to:

2.1 *Pre-Clinical and Clinical Study Transparency*

- *Requirements for companies to disclose pre-clinical developmental and reproductive toxicity (DART) studies that assess teratogenic risk.*
- *Obligations to publicly register and report clinical trial results that include teratogenicity endpoints, including timelines and public registries used.*

2.2 *Labelling, Risk Communication, and Pregnancy Guidance*

- *Mandatory requirements for companies to include teratogenic risk information in product labelling, patient safety leaflets, pregnancy warnings, or healthcare professional materials.*
- *Whether plain-language pregnancy exposure guidance and teratogenic risk summaries must be provided to the MHRA and made publicly available.*

2.3 *Post-Marketing Surveillance and Safety Reporting*

- *Obligations of Marketing Authorisation Holders (MAHs) to report reports of congenital anomalies or suspected teratogenic outcomes in pharmacovigilance systems (e.g., Yellow Card reporting).*
- *Timelines, formats, and public disclosure expectations for such post-marketing safety reports.*

2.4 *Anonymised Data Sharing and Accessibility*

- *Whether companies are required to share anonymised individual-level teratogenicity data or study datasets with the MHRA and, if so, whether there is an expectation for such data to be made available to the public or research community.*

2.5 *Conflict of Interest and Industry Conduct Transparency*

- *Expectations or requirements relating to transparency of industry involvement in research, advisory committee participation, or funding associated with teratogenicity studies.*

3. *Public Access to Teratogenicity Information*

3.1 *Public Platforms and Accessibility*

- *Please specify which platform(s) the MHRA uses to make teratogenicity-related regulatory information available (e.g., public registers, databases, safety update pages) and how individuals can access this information at no cost.*

3.2 *Format and Clarity*

- *Whether the MHRA has commitments to publish information about teratogenic risk in readily understandable formats for patients, researchers, clinicians, and the public (e.g., plain language summaries, structured risk tables).*

4. *Request for Documents and Policies*

I respectfully request copies (or links) to the following MHRA documents, policies, and guidance:

1. *MHRA's current policy on transparency of teratogenic risk assessments and communications.*
2. *Regulatory guidance on teratogenicity data expectations from pharmaceutical companies (pre-clinical, clinical, post-marketing).*
3. *Policy or guidance documents regarding public disclosure of teratogenicity data and safety signals.*

4. *Any internal standards or frameworks used by MHRA to evaluate and disclose teratogenic risk information"*

MHRA Response

We have dealt with your request under the Freedom of Information Act 2000 (FOIA). We will address each of your questions in turn:

1.1. Regulatory Communication of Teratogenic Risks

The assessors within the relevant assessment teams evaluate the data submitted by the marketing authorisation holder (MAH) and communicate any deficiencies by raising Request for Information (RFI) during the assessment stage. Following consideration of the responses and further data submitted, the approval of the Marketing Authorisation (MA) may be recommended and data regarding the benefits and risks of the medicine are reflected in the product information.

The risk assessments of potential teratogenic effects (including pre-clinical and clinical evidence) are communicated through the Public Assessment Reports (PARs) which represent the non-confidential parts of the MHRA assessment reports. PARs for refused/approved marketing authorisation applications (MAAs) are published on the MHRA Products Portal. These can be accessed via this link: https://products.mhra.gov.uk

If there is a potential teratogenic effect this is specified in the Summary of Product Characteristics (SmPC) and Patient Information Leaflet (PIL) (also available on the above link). This may be presented as a contraindication in pregnancy with associated warnings that the product should not be used during pregnancy. Medicines associated with a significant risk of harm if used during pregnancy, may have additional measures such as a Pregnancy Prevention Programme (PPP) that outline the conditions of use and the measures needed to minimise the risk.

The PARs and product information are published at the time of authorisation, and the Products Portal is updated with each regulatory change throughout the product's lifecycle. The version on the portal should therefore always be the most up to date.

If a medicine is associated with additional risk minimisation measures, healthcare professionals are informed, either by a letter at the time the product is launched or communications when the measures are introduced. This is typically via a Dear Healthcare Professional Communication and or an article in the MHRA's safety bulletin "Drug Safety Update".

1.2. Publication of Safety Information

The MHRA does not routinely publish information on potential safety signals identified from post-marketing surveillance while these are being evaluated; this applies to all safety signals and not just those relating to potential teratogenicity.

Information is communicated to healthcare professionals if a safety concern is verified. A Drug Safety Update is used to inform healthcare professionals of safety issues or concerns, particularly those that require a change in clinical practice to minimise the risk. A Dear Healthcare Professional Communication may also be used to communicate safety issues. National Patient Safety Alerts are used to communicate significant safety issues that require the healthcare system to respond.

NHS England publishes information from their Medicines and Pregnancy Registry which monitors usage of antiseizure medicines, including patients accessing maternity services. Public Health Scotland also publish similar data from the Congenital and Rare Conditions Registry Service for Scotland.

1.3. Evidence Summaries and Decision Rationales

As mentioned in the response to point 1.1, SmPCs, PILs and PARs including summaries or detailed rationales explaining how decisions involving teratogenic risk were reached, are available on the MHRA Products Portal. The SmPCs are intended for healthcare professionals and the PIL reflects the information in plain language for patients.

The SmPC and PIL for a granted marketing authorisation is readily available once the medicinal product is approved on the MHRA's Product portal, marketing authorisation holders' websites or the electronic medicines compendium. The production of PARs for new licences is a high-level performance target at the MHRA, with a target to publish within 60 calendar days of grant or refusal of a marketing authorisation.

1.4. Patient and Public Engagement

The MHRA tailors communications to meet the needs of stakeholders depending on the issue and its potential impact. The MHRA does not have separate procedures for engagement on teratogenic risk. Engagement with patients, advocacy groups, healthcare professionals and the public may depend on the product, its place in clinical practice and whether the risk is identified before the product is granted a marketing authorisation or identified through post-marketing surveillance.

For communications in in Drug Safety Update the MHRA's Patient, Public and Stakeholder Engagement (PPSE) team advise on strategy to involve patients, public representatives and stakeholders in relation to relevant articles.

The MHRA does not have any stakeholder groups which are specifically to address the teratogenic risk. However, to assist the introduction of the pregnancy prevention programme for valproate, the MHRA established the Valproate Stakeholder Network which has expanded over time to include representatives from all interested parties. The Valproate Stakeholder Network has provided feedback on patient facing materials and communications. The MHRA reached out to all relevant stakeholder groups that we could identify with an interest or expertise related to valproate and invited representatives to attend. Although limits have been applied to the number of representatives from each group that could attend meetings, no restrictions have been applied to the number of relevant groups who wished to attend.

1.5. Confidentiality vs Public Interest

When it comes to the disclosure of information/documents, we release information in accordance with the Heads of Medicines Agencies/European Medicines Agency (HMA/EMA) guidance on transparency. Please see a link to this guidance: Microsoft Word - HMA-EMA guidance

The SmPCs, PILs and PARs are published. Generally, individual papers considered by the Expert Advisory Committees are not published but the minutes of those meetings are published. PARs may be published for some safety assessments, but this is considered on a case-by-case basis, taking into account the potential public interest.

2. Transparency Obligations Imposed on Pharmaceutical Companies Related to Teratogenicity

2.1. Pre-Clinical and Clinical Study Transparency

As part of the data requirements that companies must fulfil with when applying for a marketing authorisation, companies are obligated to comply with a set of internationally recognised testing guidelines, including those that deal specifically with developmental

toxicity are reproductive toxicity (including teratogenicity). The guidelines that companies must comply with are:

- ICH M3 (R2) Non-clinical safety studies for the conduct of human clinical trials for pharmaceuticals
- ICH S5 (R3) Guideline on detection of reproductive and developmental toxicity for human pharmaceuticals
- Risk assessment of medicinal products on human reproduction and lactation: from data to labelling - Scientific guideline

As companies are required to follow the testing strategies outlined in these guidelines and generate the relevant data. It allows the MHRA to understand the fertility, embryo-foetal development, and postnatal development risks associated with the use of a medicine both at the marketing authorisation and clinical trial stage.

In relation to the transparency of reporting of teratogenic findings, full study reports are required to be submitted for any DART studies that are conducted and presented in the Non-clinical Overview. Additionally, if DART studies form part of the pivotal data submitted as part of a marketing authorisation application, these must be completed in compliance with good laboratory practice (GLP). If a reproductive risk is identified in a non-GLP study, high-quality scientific standards must still be applied, and the full study report available. For example, where a company claims that a product does not represent a reproductive or developmental risk to patients, this product will not be approved for use until the data supporting this claim is made available.

In terms of requirements for clinical study transparency, clinical trials of investigational medicinal products (CTIMPs) are required to be registered in a public and World Health Organisation (WHO) compliant registry. As part of the study registration, it requires details about the study design, including the intervention, risks, and primary/secondary outcomes (which would include teratogenicity) and monitoring processes. A link to the WHO trial registration data set can be found here: https://www.who.int/tools/clinical-trials-registry-platform/network/who-data-set. This outlines the minimum amount of trial information that must appear in a register in order for a given trial to be considered fully registered.

2.2. Labelling, Risk Communication, and Pregnancy Guidance

MHRA provides guidance which explains the legal framework for labelling and packaging as described in UK legislation and gives best practice for producing medicines labelling and packaging to ensure that medicines can be used safely by all patients, the public and healthcare professionals alike. It also reflects the expectations of healthcare professionals, patients and regulators with respect to reduction in medication errors, and safe selection and use of medicines by all users. Here is the link to this guidance: Best practice in the labelling and packaging of medicines

Marketing Authorisation Holders must follow good pharmacovigilance practices, guidance on the various aspects including requirements for safety communication are provided on the European Medicines Agency website. Here is the link to this guidance: Good pharmacovigilance practices (GVP) | European Medicines Agency (EMA).

There is currently no specific requirement for plain-language pregnancy exposure guidance or teratogenic risk summaries to be provided to the MHRA for onward publication.

2.3: Post-Marketing Surveillance and Safety Reporting

The Good pharmacovigilance practices, referred to in point 2.2, also outlines the requirements for marketing authorisation holders to submit reports of suspected adverse effects including congenital abnormalities or teratogenic effects via reporting systems within the country they occurred. In the UK, this would be the Yellow Card scheme.

The marketing authorisation holders have a requirement to inform regulatory authorities about any safety issue which may have an impact on the balance of benefits and risks for their products.

2.4: Anonymised Data Sharing and Accessibility

In addition to the individual reports, referred to in point 2.3, periodic safety update reports (PSUR) produced by the marketing authorisation holders hold summaries of this data as well as information obtained from published literature. The PSURs are held by the MHRA and are not routinely published.

Summaries of the Yellow Card data are available on the MHRA's website as Drug Analysis Profiles (iDAPs). Here is a link to the iDAPs which are available for each active substance: https://yellowcard.mhra.gov.uk/idaps.

2.5: Conflict of Interest and Industry Conduct Transparency

The majority of research is led by the pharmaceutical industry as they conduct studies on products they are developing or monitoring. Funding is declared.

The Commission on Human Medicines webpage (https://www.gov.uk/government/organisations/commission-on-human-medicines) provides information on the membership of the MHRA's advisory committees. The policy papers include the code of practice for the Expert Advisory Committees.

3: Public Access to Teratogenicity Information

3.1: Public Platforms and Accessibility

As mentioned in point 1.1 (https://products.mhra.gov.uk/), MHRA publishes the product information and public assessment reports for each new authorisation. If products are associated with a teratogenic risk, the relevant information is within those documents. Relevant communications to healthcare professionals are published in Drug Safety Update.

These documents along with the Drug Analysis Profiles are available online at no additional cost.

3.2: Format and Clarity

This has been addressed under 1.1 & 1.3.

4: Request for Documents and Policies

1. Link provided under 1.5.
2. Link provided under 2.2
3. We do not have separate specific policy or guidance regarding public disclosure of teratogenicity data or safety signals

4. We do not have specific internal standards or frameworks to specifically evaluate and disclose teratogenic risk information identified from post-marketing surveillance.

This concludes our response.

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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