Medicines & Healthcare products Regulatory Agency

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[redacted]

Our Ref: **FOI2026/00180**

15 April 2026

Dear [redacted]

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

> *"I am writing to request information regarding what formal commitments, obligations, and enforceable standards pharmaceutical companies are required to make, or are expected to meet, in order to bring an end to teratogenicity associated with medicinal products. For the purposes of this request, teratogenicity refers to preventable congenital, developmental, neurological, and lifelong harms arising from exposure to medicinal products before or during pregnancy, including where risks were known, foreseeable, or subsequently established.*
> *I respectfully request clarification on the following:*
> *1. Commitments Required of Pharmaceutical Companies*
> *1.1 What explicit commitments are pharmaceutical companies required to make to the MHRA to prevent, minimise, and ultimately eliminate teratogenic harm associated with their products?*
> *1.2 Are companies required to commit to active prevention, rather than risk management alone, where teratogenic potential is identified?*
> *1.3 What obligations exist to ensure that companies prioritise elimination of harm over commercial continuation of products with known teratogenic risk?*
> *2. Pre-Clinical, Clinical, and Post-Marketing Responsibilities*
> *2.1 What commitments must companies make regarding:*
> - *Robust pre-clinical reproductive and developmental toxicity testing*
> - *Transparent reporting of teratogenicity findings*
> - *Prompt action when safety signals emerge*
>
> *2.2 Are pharmaceutical companies required to commit to continuous reassessment of teratogenic risk throughout a product's lifecycle?*
> *3. Transparency and Disclosure Commitments*
> *3.1 What commitments do companies make to full transparency of teratogenicity data, including:*
> - *Pre-clinical and clinical study findings*
> - *Post-marketing surveillance data*
> - *Pregnancy exposure outcomes*
>
> *3.2 Are companies required to provide plain-language information to patients and the public regarding teratogenic risks and prevention measures?*

4. Accountability and Enforcement

4.1 What mechanisms does the MHRA have in place to ensure that commitments to end teratogenicity are:

- *Enforceable*
- *Audited*
- *Subject to sanction where breached*

4.2 Are companies required to demonstrate learning from historical teratogenic harm and to implement measures to prevent recurrence?

5. Documentation

Please provide copies or links to any:

- *Regulatory guidance*
- *Codes of practice*
- *Ethical frameworks*
- *Enforcement policies*

that define or govern pharmaceutical company commitments to preventing and ending teratogenic harm.

Thank you for your attention to this request. I look forward to your response in line with principles of transparency, patient safety, and public protection."

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. Commitments Required of Pharmaceutical Companies

1.1. Marketing Authorisation Holders (MAHs) must undertake robust pre-clinical and clinical studies to evaluate the safety and efficacy of their products.

The results of the studies are reflected in the product information which consists of the Summary of product characteristics (SmPC) for healthcare professionals and the Patient Information Leaflet (PIL) which is supplied in each pack of medicine.

If a teratogenic risk is identified, the medicine is generally contraindicated in pregnancy, unless there is no other effective or tolerated treatment available.

Risk minimisation measures are put in place to facilitate the safe and effective use of medicines by healthcare professionals, patients and their carers or guardians. The MHRA may request that MAHs produce risk minimisation measures as a condition for issuing a product licence, or as an outcome of the findings of a safety review into a particular risk. A Pregnancy Prevention Programme (PPP) may be put into place when a medicine has a known or potential teratogenic effect. Decisions on whether to implement a PPP are made only after consultation with independent experts such as the Commission on Human Medicines (CHM).

It may not be possible for MAHs to completely eliminate the teratogenic harm associated with their product. Healthcare professionals must discuss the risks with their patients as well as the benefits of treatment to ensure they are able to make an informed decision about the treatment.

1.2. Identification of teratogenic risks may stop further development of the product or could result in the medicine being removed from the market if there are safer alternatives available.

Teratogenic risks identified from post-marketing surveillance where there is an established clinical need for the medicine will result in risk minimisation or risk management measures. This is considered on a case-by-case basis with input from independent advice from expert advisory committees.

1.3. As outlined in Good Pharmacovigilance Practice guidelines (https://www.ema.europa.eu/en/human-regulatory-overview/post-authorisation/pharmacovigilance-post-authorisation/good-pharmacovigilance-practices-gvp), MAHs are required to monitor the safety of their products and ensure appropriate warnings are in place.

Regulatory authorities such as the MHRA, ultimately make the decision about whether the potential benefits of treatment outweigh the risks, including whether action can be taken to minimise the risks, rather than a commercial decision by the MAH.

2. Pre-Clinical, Clinical, and Post-Marketing Responsibilities

2.1. Non-clinical

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 and reproductive toxicity (DART), 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

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, DART studies if they form part of the pivotal data 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 made 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.

ICH guidelines (as referred to in previous responses) ensure that reproductive and developmental toxicity studies are scientifically robust. Additionally pivotal pre-clinical studies must be GLP compliant. GLP compliant bodies are governed by the “Good Laboratory Practice Regulations 1999”, which mandate that non-clinical health and environmental safety studies—such as toxicology and pharmaceutical research—adhere to rigorous quality standards. Compliance is monitored by the UK GLP Monitoring Authority (GLPMA), part of the MHRA.

Clinical

The “Medicines for Human Use (Clinical Trials) Regulations 2004” forms the backbone for transparency in clinical trials of investigational medicinal products (CTIMPs). They require companies to disclose any safety information, including teratogenic findings or signals, to the MHRA and ethics bodies. This regulation also states that Good Clinical Practice is a legal requirement in the UK for clinical trials of

investigational medicinal products (CTIMPs). The documentation of all reproductive and developmental toxicity findings must be present in trial master files and investigator communications.

Post-marketing

Post-marketing responsibilities are outlined in the Good Pharmacovigilance Practice guidelines, referred to in point 1.3. This includes reporting requirements and action on identified safety signals.

2.2. MAH must continuously monitor the safety of their products and investigate all potential safety concerns identified, including possible teratogenic risks. However, MAHs are not required to repeat studies looking at the teratogenic risk unless new evidence emerges.

3. Transparency and Disclosure Commitments

3.1. ICH guidelines (as referred to in previous responses) ensure that reproductive and developmental toxicity studies are scientifically robust. Additionally pivotal pre-clinical studies must be GLP compliant. GLP compliant bodies are governed by the "Good Laboratory Practice Regulations 1999", which mandate that non-clinical health and environmental safety studies—such as toxicology and pharmaceutical research—adhere to rigorous quality standards. GLP compliance requires that all raw data generated is fully documented and recorded. Therefore, this means any finding favourable or not, must be recorded. Compliance is monitored by the UK GLP Monitoring Authority (GLPMA), part of the MHRA.

The "Medicines for Human Use (Clinical Trials) Regulations 2004" form the legal backbone for transparency in clinical trials of investigational medicinal products (CTIMPs). They require companies to disclose any safety information, including teratogenic findings or signals, to the MHRA and ethics bodies. This regulation also states that Good Clinical Practice is a legal requirement in the UK for clinical trials of investigational medicinal products (CTIMPs). The documentation of all reproductive and developmental toxicity findings must be present in trial master files and investigator communications.

Details of all suspected adverse reactions, including those associated with exposure during pregnancy received by MAHs must be reported to the MHRA if they occurred in the UK. Details of the reports received through the Yellow Card scheme from all sources are available on the MHRA's website as Drug Analysis Profiles (https://yellowcard.mhra.gov.uk/idaps).

3.2. The PIL provides plain-language information about each medicine and is provided for patients in each pack of medicine. If a medicine is associated with a teratogenic risk, additional risk minimisation measures may be provided. The inclusion of additional measures such as a plain-language brochure explaining the risks is considered on a case-by-case basis depending on the level of risk.

4. Accountability and Enforcement

4.1. It is not possible to commit to end teratogenicity associated with medicines, however, measures are in place to minimise these risks and ensure that patients are fully informed about the risks associated with a treatment before they are prescribed it.

4.2. The MHRA considers each marketing authorisation and ensures the data available is reflected in the product information and any associated risk minimisation measures,

learning from previous action. Individual MAHs may not be fully aware of the action and engagement undertaken by other MAHs for other products.

5. Documentation

- Regulatory guidance regarding pharmacovigilance requirements – link provided in point 1.3
- The Code of Practice for Expert Advisory Groups is available of the CHM's webpage – link provided in point 1.1

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.

Re-use of our information