



Medicines & Healthcare products Regulatory Agency

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

Our Ref: **FOI2025/01127**

18 September 2026

Dear [REDACTED]

Thank you for your Freedom of Information (Fol) request received on 27 October 2025. You wrote:

'Under the Freedom of Information Act, I would like to request the clinical overview and the bioequivalence study report for: Ferrous fumarate 210 mg tablets PL 51463/0129 approved on 13 September 2024 submitted under Regulation 51B of The Human Medicines Regulation 2012, as amended (previously Article 10(1) of Directive 2001/83/EC. I understand that commercially confidential and personal data within any documents provided may be redacted and this is considered acceptable.'

MHRA Response

The Agency has completed its search for the information you have requested and we are able to confirm that we hold the information requested.

A copy of the clinical overview and bioequivalence study report are attached to this response.

Please note that some of the information within these documents cannot be disclosed and has been redacted. Third party consultations were sought on these documents, and the information is being exempt from release for the reasons below.

- **Section 40(2) – Personal Data**

We are unable to provide you with some of the information requested as it constitutes personal data of someone other than yourself and as such, it is being withheld in accordance with section 40(2) of the Freedom of Information Act.

Section 40(2) exempts information in response to a request if it is personal data belonging to an individual other than the requester and it satisfies one of the conditions listed in the legislation. In this case the condition contained in section 40(3A)(a) applies - that disclosure would breach one of the data protection principles, specifically that "Personal data shall be processed lawfully, fairly and in a transparent manner...".

We do not consider that disclosing this information is necessary or justified in order to satisfy your information request and the requirements of the Fol Act. In relation to this request, we consider that there is no strong legitimate interest that would override the prejudice to the rights and freedoms of the data subject.

Personal data are subject to UK General Data Protection Regulation (UK GDPR) and the Data Protection Act 2018.

MHRA maintains the following policy on disclosure of personal information:

"All personal information held in MHRA records is regarded as confidential. Information will not normally be disclosed to third parties without the consent of the person concerned. Information may normally be disclosed without consent to meet statutory requirements; to comply with a court order; to prevent duplication of payments from public funds; or where there is a compelling public interest in making the disclosure."

All disclosures made by MHRA, in order to be considered authorised, must be able to demonstrate that at least one of the above criteria apply.

- **Section 41:**

Section 41 indicates that 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 41(1) of the FoI Act protects information provided in confidence. Some of the redacted information relates to information provided in confidence by the Marketing Authorisation Holder when submitting the product application. The Agency believes that if this information would be released it would breach the confidence of the persons the information pertains to, actionable by them or any other person. Therefore, this is redacted in the documents for release.

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

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/>