Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

[redacted]

MHRA

10 South Colonnade
Canary Wharf
London
E14 4PU
United Kingdom

www.gov.uk/mhra

30 April 2024

Dear [redacted]

RE: FOI 24/322

Thank you for your information request, dated 2 April 2024, where you asked for further information on the 5 ferric derisomaltose reports, reported by your trust, which were included in the previous response (24/174). Your exact request is detailed below:

"I should be grateful if I can have further details on the reactions reported for:

Ferric derisomaltose.

Would it please be possible to have all 5 reports."

Details from adverse incident reports such as patient and reporter details are exempt from disclosure under Section 40 (personal information) and Section 41 (information provided in confidence) of the FOIA. Supplying you with this information could lead to patient identification. Further to the use of Section 40 and 41, as outlined in our Privacy Policy, the MHRA will not share the identity of anyone submitting a Yellow Card report with any person outside the MHRA without their explicit consent, unless we are required or permitted to do so by law. As this is personal data in relation to an individuals' health, this would be of detriment to them and may damage the engagement with the scheme. As such we are unable to share the reports in full.

However, under section 16 of the FOIA, duty to assist, the following information can be provided as aggregated data or summary ifnormation:

- All 5 reports were received by the MHRA in 2023.
- Four of the adverse reaction reports concerned female patients and 1 concerned a male patient.
- Four reports were reported by nurses and 1 reported by a midwife.
- Age was provided within 3 out of 5 reports. Age ranges for the 3 patients were 70-79, 50-59, and 30-39.

- Time to onset of the reaction was provided within 4 reports, all of which reported the reaction to have started within 24 hours.
- No other drugs were reported alongside ferric derisomaltose in any of the reports.
- Details of the adverse reactions reported and the reported outcomes in each case can be found below in Table 1.

Table 1: Reactions and outcomes for UK spontaneous suspected adverse reaction reports from The Rotherham NHS Foundation Trust, S60 2UD, where the suspect drug was ferric derisomaltose.

Case	Reaction(s) + Outcome(s)
1	Anaphylactic reaction (Recovered/resolved)
2	Chest discomfort (Recovered/resolved), Vomiting (Recovered/resolved)
3	Anaphylactic reaction (Recovering/resolving)
4	Chest pain (Recovered/resolved), Hypotension (Recovered/resolved), Somnolence (Recovered/resolved)
5	Oxygen saturation decreased (Recovering/resolving)

When considering the provided spontaneous Adverse Drug Reaction (ADR) data, it is important to be aware of the following points:

- A reported reaction does not necessarily mean it has been caused by the drug, only that the reporter had a suspicion it may have. The fact that symptoms occur after use of a drug, and are reported via the Yellow Card scheme, does not in itself mean that they are proven to have been caused by the drug. Underlying or concurrent illnesses may be responsible and such events can also be coincidental.

- It is also important to note that the number of reports received via the Yellow Card scheme does not directly equate to the number of people who suffer adverse reactions and therefore cannot be used to determine the incidence of a reaction. ADR reporting rates are influenced by the seriousness of ADRs, their ease of recognition, the extent of use of a particular drug, and may be stimulated by promotion and publicity about a drug. Reporting tends to be highest for newly introduced medicines during the first one to two years on the market and then falls over time. For these reasons the enclosed data should not be used as a basis for determining incidence of side effects.

If you are dissatisfied with the handling of your request, you have the right to ask for an internal review. Internal review requests should be submitted within two months of the date of this response; and can be addressed to this email address.

Yours sincerely,

Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

FOI Team,
Safety and Surveillance

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If you have a query about the information provided, please reply to this email

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review. The Information Commissioner can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF