From: Pharmacovigilanceser <vigilanceservice@mhra.gov.uk>
Sent: 03 January 2024 14:56
[redacted]
Subject: FW: FOI 23/934 - Freedom of information request - Ferinject RMP version 13.1

From: Pharmacovigilanceser <vigilanceservice@mhra.gov.uk>
Sent: Wednesday, January 3, 2024 2:54 PM
[redacted]
Subject: RE: FOI 23/934 - Freedom of information request - Ferinject RMP version 13.1

[redacted]

Thank you for your FOI request dated 30th November 2023. We can confirm that the requested RMP has not been submitted to the MHRA yet and is therefore considered not held under the FOI Act. Please note that the education materials and follow up questionnaires have not been updated as part of this procedure. Therefore the versions of these documents provided in response to your previous requests are still the most recently approved.
We are happy to provide a copy of the approved RMP once the procedure has been completed.

I hope the information provided is helpful however please do not hesitate to contact me if I can be of further assistance.

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 you receive this response and addressed to: info@mhra.gov.uk.

Kind regards,

FOI Team
Safety & Surveillance Group
Medicines and Healthcare Products Regulatory Agency
10 South Colonnade, Canary Wharf, London E14 4PU

[redacted]
Sent: Thursday, November 30, 2023 9:37 AM
To: MHRA Customer Services <MHRACustomerServices@mhra.gov.uk>; Pharmacovigilanceser <vigilanceservice@mhra.gov.uk>
Subject: FOI 23/934 - Freedom of information request - Ferinject RMP version 13.1

Dear Sir or Madam,

In connection with an ongoing procedure for marketing authorisation application for a product containing ferric carboxymaltose as an active substance, I would kindly ask you to provide me with copies of latest version, number 13.1, of the risk management plan for the reference product, Ferinject. Also I would like to ask for the educational material and follow up questionnaires approved as part of the risk management plan for the same reference product.

Thanks in advance.

Best regards,

[redacted]

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[redacted]