**FOI 23/157 – Venofer RMP**

**22 February 2023**

I would like to ask if there is an available RMP/sRMP (approved in UK) for Venofer. Please provide me with the document if possible (or at least please let me know about current list of safety concerns).

**MHRA RESPONSE**

**21 March 2023**

Thank you for your email, dated 22/02/2023, in which you requested:

“a copy of the Risk Management Plan for Venofer.”

We can confirm that the MHRA holds a copy of the requested RMP. Please note that the current RMP is undergoing an update and a new version will be available in due course.

Information that has been redacted is exempt under Section 40 (Personal Information) or Section 43 (Commercial Interests) of the Freedom of Information (FOI) Act and is therefore withheld.

Section 40 provides that personal information may be exempt from release where to do so would contravene data protection principles. Section 43 provides that information will be exempt from release where to do so would or would be likely to prejudice commercial interests. Furthermore, we do not believe that there is an overriding public interest in disclosing the redacted information in this instance.

We hope the information provided is helpful, but 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.

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

Yours sincerely,

FOI Team,
Vigilance and Risk Management of Medicines Division