

Subject: Clarifications in Relation to Vifor Pharma's Communications about Monofer in the UK

Dear Sir/Madam,

As you may know, the CMA has been investigating Vifor Pharma in relation to potentially misleading communications comparing Ferinject (ferric carboxymaltose) to Monofer (ferric derisomaltose) in the United Kingdom. This investigation has been concluded without an infringement finding against Vifor Pharma or admission of liability from Vifor Pharma. However, Vifor Pharma has agreed to a number of commitments including that Vifor Pharma disseminates this communication to you.

In the context of its investigation, the CMA raised preliminary concerns that Vifor Pharma has been disseminating potentially misleading information regarding the safety of Monofer. In this regard, Vifor Pharma makes the following clarifications in order to remove any possible confusion caused by its past communications about Monofer's safety:

- There is no scientific basis to consider Ferinject to have a superior safety profile compared to Monofer.
- There is no basis to suggest that Monofer has a limited evidence base that would call into question its safety, which is apparent from Monofer's marketing authorisation and from the successive reviews of intravenous iron medicines by the European Medicine Agency.
- Pursuant to Monofer's summary of product characteristics (SmPC), which was approved by the competent regulatory authorities, Monofer is not a dextran, dextranderived, or dextran-based product. Furthermore, Monofer does not have increased risk of hypersensitivity reactions (HSR) compared to Ferinject.

We hope that this letter clarifies any potentially misleading past communications about Monofer in the United Kingdom.

Should you have any questions about the above or about any future communications by Vifor Pharma on Monofer, please contact: <u>HCPLetter@viforpharma.com</u>.

Sincerely,

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Hervé Gisserot General Manager CSL Vifor

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