**CASE AUTH/3706/11/22** ***NO BREACH OF THE CODE***

# COMPLAINANT v CSL VIFOR

## Alleged disguised promotion of Ferinject (ferric carboxymaltose)

### CASE SUMMARY

**The complainant alleged that CSL Vifor used a non-promotional service to increase the use of its medicine Ferinject (ferric carboxymaltose) by only offering the service to hospitals that used Ferinject and not targeting accounts where its competitor, Monofer (ferric derisomaltose), was the most commonly prescribed IV iron, and that this service offering was disguised promotion of Ferinject.**

**The Panel ruled no breach of the following Clauses of the 2021 Code as it considered that the complainant had not established that CSL Vifor had used a non-promotional service to increase the use of its medicine Ferinject, nor that the service was disguised promotion of Ferinject, as alleged, noting that:**

- **the complainant provided no evidence to support his/her allegation that the service was only offered in accounts that used Ferinject and not in accounts that used Monofer as the IV iron of choice;**
- **CSL Vifor submitted that in determining the focus of activity, the principal data sources used were not current treatment related but took account of Hospital Episodes Statistics (HES) data which looked at populations within CCGs such as the incidence of high blood loss surgery and the rates of anaemia detected in that group;**
- **whilst the Panel was concerned that the service in question was proactively offered by those who had a dual promotional/non-promotional role, it appeared these staff had been briefed to separate the discussion of the service from any promotional activity;**
- **the materials in relation to the service did not refer directly or indirectly to a specific IV Iron:**

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| **No Breach of Clause 2** | **Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry** |
| **No Breach of Clause 5.1** | **Requirement to maintain high standards** |
| **No Breach of Clause 15.6** | **Requirement that promotional material and activities must not be disguised** |
| **No Breach of Clause 23.1** | **Requirement that donations are freely given for the purpose of supporting healthcare with no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return.** |

| No Breach of Clause 23.2 | Requirement that donations to healthcare organisations do not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines. |
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**This summary is not intended to be read in isolation.**
**For full details, please see the full case report below.**

**FULL CASE REPORT**

A complaint was received from an ex-employee of CSL Vifor about the company's service offered to the NHS.

**COMPLAINT**

The complainant stated that CSL Vifor undertook a mix of promotional and non-promotional work related to its iron medicine (Ferinject). The non-promotional activity was focused on developing services in NHS hospitals with the aim of increasing the provision of intravenous iron medicines to patients (increasing sales of iron and, in turn, CSL Vifor's own product). The materials associated with this non-promotional activity were all non-promotional and did not include a direct mention of Ferinject. CSL Vifor had recently started using a contract sales team who were dedicated to selling Ferinject for pre-operative anaemia. This team also had a remit to develop/increase IV iron services for pre-operative patients with anaemia as a non-promotional activity. In the complainant's opinion this was disguised promotion as the ultimate aim of this team and its activity was to increase the use of Ferinject via this non-promotional activity.

The complainant's reasons for this were: the team only targeted accounts where Ferinject was commonly used and not where a competitor, Monofer, was the most commonly prescribed IV iron. The complainant stated that CSL Vifor would say it based its targeting on data which highlighted where the greatest patient demand was. However, there was a strong correlation between CSL Vifor's targeting and the use of Ferinject. If CSL Vifor was genuinely trying to develop services to allow patients to access IV iron services, based on where the greatest need was based on patient demand, they would have a greater number of non-Ferinject accounts in which its contract team was active. This non-promotional activity/service CSL Vifor offered was only offered in hospitals where Ferinject was being used which the complainant alleged constituted a form of disguised promotion.

When writing to CSL Vifor, the Authority asked it to consider the requirements of Clauses 2, 5.1, 15.6, 23.1 and 23.2 of the 2021 Code.

**RESPONSE**

CSL Vifor submitted that no evidence had been presented to support this allegation.

CSL Vifor had investigated the complaint, taking into consideration Clauses 2, 5.1,15.6, 23.1 and 23.2 as requested and, as stipulated, under the 2021 Code.

The complainant stated that CSL Vifor was undertaking non-promotional activities and services in NHS Trusts to develop or increase intravenous iron usage for pre-operative patients with anaemia. The complainant alleged, however, that these services were only offered in those Trusts where a competitor product, Monofer, was not commonly prescribed.

The complainant acknowledged that the materials associated with these activities were 'all non-promotional and did not include a direct mention of Ferinject'.

CSL Vifor Pharma refuted the allegation.

CSL Vifor submitted that it currently offered NHS Trusts a selection of tools and resources to allow them to gather data and build their own business case for pre-operative anaemia screening and treatment services. These resources were approved for non-promotional use, as per the complainant's acknowledgement, to assist Trusts in their implementation of a key Commissioning for Quality and Innovation (CQUIN), Clinical Commissioning Group (CCG) indicator, CCG06.

The CQUIN indicator CCG06 which, itself, supported an established National Institute for Health and Care Excellence (NICE) Guideline (NG24), stated that there was a 45%-60% goal for surgical wards to both screen and treat anaemia in all patients undergoing major elective surgery.

In the CQUIN NHS documentation, CCG06 was described as follows:

> *'There is detailed NICE guidance NG24 setting out the requirements to offer iron before surgery to patients with iron-deficiency anaemia. This indicator draws attention to the importance of screening and treatment in line with that guidance and drives more consistent delivery of standard clinical practice. Improved compliance would reduce blood transfusion rate for major blood loss surgeries, reducing the occurrence of patient safety risks associated with blood transfusion including fluid overload, infection and incorrect blood transfusions being given. Overall, it is estimated that consistent uptake of screening to 60% would deliver savings of around £3m associated with units of blood being saved due to lower transfusion rates, reductions in critical care periods, saved bed days and reductions in admission rates.'*

NG24 further recommended Trusts:

> '*Offer oral iron before and after surgery to patients with iron-deficiency anaemia*.'

It then recommends to:

> '*Consider intravenous iron before or after surgery for patients who:*
>
> - *have iron-deficiency anaemia and cannot tolerate or absorb oral iron, or are unable to adhere to oral iron treatment (see the NICE guideline on medicines adherence)*
> - *are diagnosed with functional iron deficiency*
> - *are diagnosed with iron-deficiency anaemia, and the interval between the diagnosis of anaemia and surgery is predicted to be too short for oral iron to be effective*.'

CSL Vifor submitted that the CQUIN (CCG06) focused on implementation of NG24, which as stated above, in turn clearly focused on the screening as well as treatment of patients and recommends the use of oral iron as a first line treatment for patients with iron-deficiency anaemia. The resources provided by CSL Vifor, therefore, were not solely focused on the use of intravenous iron for pre-operative patients with iron-deficiency anaemia but also took account of the crucial place of oral iron in the treatment pathway.

CSL Vifor submitted that the non-promotional tools and resources offered by CSL Vifor, to assist with the assessment of current service and business case preparation to improve pre-operative anaemia screening and treatment services, was fully aligned with both the NHS CQUIN indicator and the established NICE Guidance. All materials pertaining to the service, briefing documents/training to the teams offering this provision and the Trusts who might take up the service, were non-promotional and contained no reference to a specific iron treatment either oral or intravenous.

CSL Vifor submitted that the allegation that CSL Vifor was 'targeting' accounts *where 'Ferinject is commonly used and not where a competitor Monofer is the most commonly prescribed IV iron'*, was not true as outlined below.

The primary remit of the contract team was to support the NHS to address the screening and treatment of patients with anaemia in high blood loss surgery.

In determining the focus of activity, the principal data sources used, were not current treatment-related but took account of Hospital Episodes Statistics (HES) data – which looked at populations within CCGs such as the incidence of high blood loss surgery and the rates of anaemia detected in that group.

The data was then compared with total high dose iron use by hospital, to identify gaps which would hinder the NHS in meeting CQUIN CCG06 activity targets.

CSL Vifor submitted that there was no active selection of Trusts based on the use of one or other of the two licensed rapid infusing intravenous irons, or indeed any intravenous or oral iron treatment. It was purely based on the greatest opportunity for the NHS and patients to benefit from CQUIN / NG24 implementation.

CSL Vifor submitted that it did not mix promotional and non-promotional activities, and this was clear in the materials that had been produced and the associated team briefings.

In relation to the clauses requested by the PMCPA to be considered, CSL Vifor submitted that:

- the provision of the services offered were freely provided in the support of healthcare with no consequent obligation on the Trusts who might choose to take up the service to use Ferinject.

  **A breach of Clause 23.1 was refuted.**

- Further the services offered were prospective in nature, did not bear the name of a CSL Vifor product, did not constitute an inducement to prescribe/recommend a specific medicine and required a written and signed agreement for its provision.

  **A breach of Clause 23.2 was refuted.**

- The services were provided on a non-promotional basis supported by clear briefing, service provision/training documentation and service agreements.

  No reference to CSL Vifor products was made and as the complainant acknowledged, *'The materials associated with this non-promotional activity are all non-promotional and don't include a direct mention of Ferinject'.*

  **A breach of Clause 15.6 was refuted.**

- The service provision was supported by comprehensive briefing, service provision/training documentation and agreements. All materials had undergone a full review and certification.

  **A breach of Clause 5.1 was refuted.**

- As a consequence of no constituent Clauses having, in CSL Vifor's view, been breached and the service provision offered by the company being fully aligned with both the NHS' CQUIN indicator CCG06 and the established NICE Guidance NG24, **CSL Vifor rejected a breach of Clause 2**.

In summary, CSL Vifor did not believe that the allegation in the complainant's letter was substantiated and, in consequence, denied breaches of Clauses 23.1, 23.2, 15.6, 5.1 or 2 of the 2021 Code.

**PANEL RULING**

The Panel noted the complainant's allegation that CSL Vifor used a non-promotional service to increase the use of its medicine Ferinject (ferric carboxymaltose) by only offering the service to hospitals that used Ferinject and not targeting accounts where its competitor, Monofer (ferric derisomaltose), was the most commonly prescribed IV iron, and that this service offering was disguised promotion of Ferinject.

Ferinject was indicated for the treatment of iron deficiency when:

– oral iron preparations are ineffective.

– oral iron preparations cannot be used.

– there is a clinical need to deliver iron rapidly.

The diagnosis of iron deficiency must be based on laboratory tests.

The Panel noted CSL Vifor's submission that it currently offered NHS Trusts a selection of tools and resources to allow them to gather data and build their own business case for preoperative

anaemia screening and treatment services to assist Trusts in their implementation of a key Commissioning for Quality and Innovation (CQUIN), Clinical Commissioning Group (CCG) indicator, CCG06.

The Panel queried CSL Vifor's submission that the resources it provided did not solely focus on the use of intravenous (IV) iron for preoperative patients with iron-deficiency anaemia but also took account of the crucial place of oral iron in the treatment pathway.

In this regard, the Panel noted that the briefing document for the engagement teams titled 'Business case resource' (UK-NP-2200023) stated on the second slide, objective, *'Its purpose is to assist and inform NHS clinical, managerial, business and support staff, in creating a compelling business case for an IV iron infusion service and in planning and implementing such a service. It is a comprehensive resource designed to bring together information, evidence and insights, which may be helpful when considering submission of a business case for an intravenous iron service.'* This briefing further stated that this resource sits within a portfolio of materials, designed to support NHS stakeholders wishing to develop and optimise IV iron services.

The Panel considered that the service related materials provided appeared to solely focus on IV iron, which was evident from the material headings including: 'Intravenous Iron Infusion - Discharge Template' (UK-NP-2100181); 'Pre-Operative Anaemia: Intravenous Iron Service Explorer' (UK-NP-2100175); 'Nurse support for intravenous iron infusion services' (UK-NP-2200077); and the 'Safety Considerations and Resources for IV Iron Infusion Services' (UK-NP-2100155). Even within the material titled 'Service Optimisation for patients with Iron Deficiency Anaemia in the preoperative arena' (UK-NP-2100162), the third slide was headed 'The value of IV iron in the preoperative arena' and appeared to focus on the value of IV iron therapy with only very brief mention of oral iron.

The Introducing Service Optimisation (UK-NP-2100258) slides were sub headed 'An overview of Vifor support, available to the NHS, for PBM [patient blood management] Intravenous Iron Services' followed by the statement 'Provision of this service does not recommend or expect the use of any specific iron product'. This latter statement also appeared at the bottom of slides 2 and 8. Slide 7 stated that support may be available in the form of collaborative working, donations or benefit in kind services. Slide 8 stated:

> 'If you require additional short term service support - for example;
> - to facilitate cross team working or chair meetings
> - model a series of service options
> - build a business case
> - explore alternative clinic options
>
> our PBM Engagement Team may be able to work with you. This kind of service support in the form of staff time, experience or expertise can be requested as a Donation 'Benefit in Kind' (ABPI Code Clause 23).'

Clause 23.1 stated, amongst other things, that donations and grants were funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return.

Clause 23.2 included that donations and grants to healthcare organisations were only allowed if they did not constitute an inducement to recommend and/or prescribe, purchase, supply, sell or administer specific medicines.

The supplementary information to Clause 23 included that companies should be clear regarding the role of staff in the provision of donations, particularly the role of representatives. Companies should consider using staff other than representatives. If companies decide to use representatives in relation to donations, then this should be in accordance with certain principles including that representatives may introduce a donation by means of a brief description and/or delivering materials but may not instigate a detailed discussion about the donation at the same time as a call or contact at which products are promoted and the donation must not be linked in any way to the promotion of products. In order to comply with this, the representative must not carry out both activities at the same call or contact.

The Panel noted that the briefing document for the engagement teams titled 'Business case resource' (UK-NP-2200023) stated that whilst the material could be used proactively, it had to be used in a non-promotional capacity separate from any promotional activity and must not include any recommendation or advice to use a particular IV iron product.

The Panel noted that CSL Vifor was not the only company that had an IV iron product, however, the company clearly had a commercial interest in this area and would stand to benefit from the establishment of additional IV iron services in hospital Trusts as this would likely lead to an increase in use of their product, Ferinject, as well as other IV iron products. One of the questions to be considered was whether the service was targeted such that it would likely lead to the use of a particular IV iron.

The basis for a pharmaceutical company's decision regarding in which geographical areas and hospital Trusts a service would be offered, was important. It would likely be inappropriate to offer a service only in Trusts in which the company's medicine was not precluded or was the only or known recommended treatment choice.

The Panel noted CSL Vifor's submission that in determining the focus of activity, the principal data sources used, were not current treatment related but took account of Hospital Episodes Statistics (HES) data - which looked at populations within CCGs such as the incidence of high blood loss surgery and the rates of anaemia detected in that group. The data was then compared with total high dose iron use by hospital, to identify gaps which would hinder the NHS in meeting CQUIN CCG06 activity targets.

The Panel further noted CSL Vifor's submission that there was no active selection of Trusts based on the use of one or other of the two licensed rapid infusing intravenous irons, or indeed any intravenous or oral iron treatment; it was purely based on the greatest opportunity for the NHS and patients to benefit from CQUIN / NG24 implementation.

Whilst the Panel was concerned that the service in question was proactively offered by those who had a dual promotional/non-promotional role, it appeared these staff had been briefed to separate the discussion of the service from any promotional activity. However, the Panel queried whether the briefing was adequate on certain matters whilst noting these were not matters raised by the complainant.

The Panel did not have any data before it regarding which hospital Trusts the service in question had been offered to and the corresponding use of Ferinject, prior to, or post the service.

The Panel noted that the 'Nurse support for IV iron infusion services' slides (UK-NP-2200077) referred to a maximum 6-month period for the service provision and referred to monthly review meetings between the third party agency and the NHS Trust to review data regarding service (aggregated and anonymised) to confirm criteria/KPIs were met and service could continue and a final meeting to review all data to support the site in considering future service provision. It was not clear what service data, if any, was reported to CSL Vifor. The Panel did not have before it an example of a service level agreement as referred to in the materials.

The Panel was not an investigatory body as such. It asked the respondent company for a complete response and the complainant had the burden of proving their complaint on the balance of probabilities.

The Panel noted that the complainant provided no evidence to support his/her allegation that the service was only offered in accounts that used Ferinject and not in accounts that used Monofer as the IV iron of choice.

Whilst noting the seriousness of the allegation, the Panel considered that the complainant had not established that CSL Vifor had used a non-promotional service to increase the use of its medicine Ferinject by only offering the service to hospitals that used Ferinject and not targeting accounts where its competitor Monofer was the most commonly prescribed IV iron, and the Panel therefore ruled **no breach of Clauses 23.1 and 23.2**.

Noting the above, and that the materials provided by CSL Vifor in relation to the service did not refer directly or indirectly to a specific IV Iron, the Panel considered that the complainant had not established that the service was disguised promotion of Ferinject and **no breach of Clause 15.6** was ruled.

Noting the above rulings of no breaches of the Code, and the absence of evidence before it, the Panel consequently ruled **no breach of Clauses 5.1 and 2**.

**Complaint received** **14 November 2022**

**Case completed** **17 August 2023**