

CASE AUTH/3301/1/20

ANONYMOUS v VIFOR

Promotion of Ferinject

An anonymous, contactable individual complained that the ivironheart.co.uk website (ref UK-NP-1900153, September 2019) was disguised promotion of Vifor Pharma UK's product Ferinject (ferric carboxymaltose). Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

The complainant alleged that an employee's conduct led to pressure on signatories. Promotion related to both direct and indirect reference to products and Vifor had products which were intravenous (IV) iron preparations eg Ferinject. Ferinject also had evidence within cardiac patients (section 5.1 of the Ferinject summary of product characteristics (SPC) referred).

The complainant alleged that the ivironheart website aimed at health professionals looked and felt promotional with numerous claims about IV iron. The website was not fair and balanced in that it described the disadvantages of oral iron therapy but only the positives of IV iron therapy in relation to cardiovascular outcomes. The complainant alleged that, given the way the information was falsely presented, readers could assume that IV iron had no side effects. The complainant stated that there should be prescribing information and adverse event reporting and queried whether the website had been certified.

The detailed response from Vifor is given below.

The Panel noted Vifor's submission that the website was a non-promotional, medical educational website aimed at health professionals' to raise awareness of the role of iron in the heart, explain why heart failure patients might be iron deficient and to provide information on the consequences of iron deficiency for heart failure patients. It included reference to the treatment (both oral and intravenous) of iron deficiency in heart failure noting that oral iron, was considered to be of limited benefit in heart failure.

The Panel noted that it appeared that the site was intended for healthcare professionals treating patients with iron deficiency in chronic heart failure.

In the Panel's view the imagery and claims for IV iron and statements about oral iron appeared to be of the type generally associated with promotion. The Panel considered that the content of the Vifor website, including the claims for IV iron and the reasons not to use oral iron was promotional for Vifor's IV iron products.

The Panel disagreed with Vifor's submission that the reference to IV irons generally on the website was not a reference, either direct or indirect, to any specific medicine. There were references to specific medicines in the material, these being oral and IV treatments

for iron deficiency. In the Panel's view the website promoted IV iron and Vifor marketed two IV iron preparations, namely Ferinject and Venofer. The website could not be considered anything other than promotional for those medicines.

The Panel then went on to consider the matter in relation to Vifor's subsequent submission that it had discovered that there was a link between the ivironheart.co.uk website and a promotional item, Vifor's global cardiology awareness campaign sales aid (ref UK-FCM-1800049) which included promotional information in relation to Ferinject. The briefing material for this sales aid (ref UK-FCM-1900051) gave background on the 'Cardiology Awareness Campaign' and referred to the purpose of the 'unbranded disease awareness campaign' as aiming to increase the number of iron deficient heart failure patients treated with IV iron, decrease the number inappropriately treated with oral iron and drive awareness of the European Society of Cardiology (ESC) diagnostic criteria for treating patients. The briefing material for the sales aid stated that the desired outcome to achieve for certain health professionals (evidence followers) was to acknowledge that Ferinject was the only iron therapy recommended by the ESC 2016 Heart Failure Guidelines and treat their patients accordingly. Representatives were instructed to switch to using the Ferinject branded sales aid once a customer believed in the value of IV iron for iron deficient heart failure patients '... and continue to differentiate and promote the unique benefits of Ferinject for heart failure patients'. The Panel noted that the ivironheart.co.uk website which contained imagery and content identical to that within the sales aid (UK-FCM-1800049) as acknowledged by Vifor appeared to be part of Vifor's campaign to promote Ferinject.

The Panel noted that the ivironheart.co.uk website did not include Ferinject or Venofer prescribing information nor did it include a clear and prominent statement as to where the prescribing information could be found. It did not include the requisite statement about reporting adverse events. The Panel therefore ruled breaches of the Code.

The Panel noted that the website had not been certified for promotional use and thus ruled a breach of the Code.

The Panel noted its comments above and did not consider that the Vifor website was disguised promotion; it was clearly promotional. The Panel therefore ruled no breach of the Code.

The Panel noted Vifor's submission that the website should contain more comprehensive information about both oral and IV irons and the website had been deactivated in order to address this. The Panel noted its comment above with regard to the content of the website in relation to the limitations of oral iron and the clinical benefits of IV iron. The Panel did not consider that the website was sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicines. The Panel further considered that the comparison between oral and IV iron portrayed by the website was misleading as alleged. Breaches of the Code were ruled.

The Panel was concerned to note that Vifor had failed to recognise that the ivironheart.co.uk website promoted its two products Ferinject and Venofer. The Panel was further concerned that this had not been picked up in relation to the Cardiology Awareness Campaign Sales Aid (UK-FCM-1800049) considering the link between the website and the sales aid and its associated briefing material. The same signatory had

certified the three pieces ie the Cardiology Awareness Campaign Sales Aid, its associated briefing and the ivironheart.co.uk website. The Panel considered that Vifor had failed to maintain high standards and a breach of the Code was ruled.

The Panel noted that the complainant had raised concerns about a Vifor employee alleging this led to pressure on the signatories. The Panel noted that the complainant bore the burden of proof and had not provided evidence to establish his/her complaint on the balance of probabilities in this regard. The Panel therefore ruled no breach of the Code.

It appeared that Vifor might have confused a non-promotional disease awareness campaign, which was usually aimed at members of the public rather than health professionals, with a promotional campaign for Ferinject. Further it appeared that Vifor staff had not fully understood the materials, their links to each other and the impact of relevant Code requirements.

Noting its comments and rulings above, the Panel considered that Vifor had brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

An anonymous, contactable individual complained that the ivironheart.co.uk website (ref UK-NP-1900153, September 2019) was disguised promotion of Vifor Pharma UK's product Ferinject (ferric carboxymaltose). Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

COMPLAINT

The complainant alleged that the ivironheart.co.uk website was disguised promotion in breach of Clauses 1.2 and 12.1 and perhaps even 14.1. The complainant submitted that an employee was not a signatory and so did not understand the principles of promotion and pushed ahead with such concepts with a lack of understanding leading to pressure on signatories. Promotion related to both direct and indirect reference to products and Vifor had products which were intravenous (IV) iron preparations eg Ferinject. Ferinject also had evidence within cardiac patients (section 5.1 of the Ferinject summary of product characteristics (SPC) referred).

The ivironheart website was aimed at health professionals; it looked and felt promotional with numerous claims about IV iron. Also the website was not fair and balanced in that it described the disadvantages of oral iron therapy but only the positives of IV iron therapy in relation to cardiovascular outcomes. The complainant alleged that, given the way the information was falsely presented, readers could assume that IV iron had no side effects. The complainant stated that there should be prescribing information and adverse event reporting so alleged this was in breach of Clauses 4.1, 4.6 and 4.9. As the information was not fairly balanced the complainant further alleged breaches of Clauses 7.2, 7.3 and 9.1.

When writing to Vifor the Authority asked it to consider the requirements of Clause 2 in addition to the clauses cited by the complainant. Vifor was advised that although it did not need to respond to Clause 1.2, as that clause defined promotion and could not be breached, it should bear the definition in mind when deciding upon the matter of disguised promotion.

RESPONSE

Vifor submitted that ivironheart.co.uk was a non-promotional, medical educational website designed to raise health professionals' awareness of the role of iron in the heart, explain why heart failure patients might be iron deficient and to provide information on the consequences of iron deficiency for heart failure patients. There was also reference to the treatment of iron deficiency in heart failure, both oral and intravenously noting that a commonly used treatment, oral iron, was considered to be of limited benefit in heart failure (Lewis *et al* 2017).

The website was certified as non-promotional on 1 October 2019 and went live on 7 November 2019. The website had been taken down but Vifor provided details of the website as it appeared on 22 January 2020.

Health professionals were told about the website by:

- Third parties
- Digital advertisement in the BMJ
- Leavepiece handed out and an advertisement in the printed programme for the British Society of Haematology, 27-28 November 2019
- Leavepiece used by Vifor representatives.

Vifor noted that the complainant appeared to consider that ivironheart.co.uk was a promotional website because Vifor had 'products which are IV iron preparations'. Vifor noted the very broad definition of promotion in the Code and the certain exceptions to that definition. Vifor submitted that the website fell within the exception of: 'Information relating to human health or diseases provided there is no reference, either direct or indirect, to specific medicines'.

The complainant alleged that the website constituted an indirect reference to Vifor IV irons, however the company refuted this. There were in total six licensed IV irons available for use in the UK: Ferinject and Venofer (Vifor), Monofer, Diafer and Cosmofer (Pharmacosmos) and SuCrofer. Vifor thus did not accept that reference to IV irons generally was a reference, either direct or indirect, to any specific medicine.

In summary, Vifor denied that the website promoted any IV iron, including those that it marketed, and denied that the website was disguised promotion in breach of Clause 12.1. As the website was not promotional it did not need prescribing information for any medicine or an adverse event reporting statement and so the company denied breaches of Clauses 4.1, 4.6 and 4.9. Given that the website was non-promotional, Clause 14.1 was not relevant, given that it referred to the certification of promotional materials; as noted above, the website was certified as non-promotional, in accordance with the requirements of Clause 14.3.

Vifor noted the complainant's concern that the content of the website was not balanced, in that it referred to certain side effects for oral iron therapy but not for IV iron treatment. In that regard, Vifor noted that the main focus of the website was to emphasise the role of iron in the heart and the importance of treating iron deficiency in heart failure patients. With hindsight, however, Vifor submitted that the website should contain more comprehensive information about both oral and IV irons and to this end, as of 28 January 2020, the website had been deactivated in order to address this. With that in mind, Vifor understood that the requirements of Clauses 7.2 and 7.3 might be relevant.

Vifor stated that as the main focus of the website was to emphasise the role of iron in the heart and the importance of treating iron deficiency in heart failure patients, rather than specifically the use of IV iron in heart failure which did not amount to a breach of either Clause 9.1 or 2.

Vifor noted that the complainant made the tenuous assumption regarding the employee. Vifor gave further details including that his/her academic qualifications and extensive experience provided ample support for his/her current role and he/she had the support of experienced final signatories within the UK business.

In addition, Vifor signatories had access to a wealth of knowledge and experience provided by other staff whom had worked in relevant positions for many years, including as final signatories. Vifor provided details of its signatory who had approved the website.

Vifor noted the complainant's implication that there was 'pressure' on signatories; he/she had not elaborated further on that point. Vifor assumed that the complainant had referred to pressure to certify material inappropriately, which the company refuted. Neither the signatory who certified the website at issue in this case, nor another available signatory within the organisation, had raised any concerns related to undue pressure or influence over their responsibilities or opinions.

Further information provided by Vifor

Further to its initial response (dated 17 February) Vifor submitted (letter dated 24 March) that it had discovered items in its approval system that were relevant to this case in relation to the content of the website <https://ivironheart.co.uk/>.

Vifor noted the complainant's allegation that the website was promotional on the grounds that Vifor had 'products which are IV iron preparations'. Vifor submitted that whilst it still considered that the content of the website as a stand-alone item was non-promotional, a recent job bag audit conducted by a third party uncovered two documents that related to a promotional educational campaign which contained information which was also included in this website. The first of these documents was an internal briefing document for Vifor's sales force on the global cardiology awareness campaign sales aid (ref UK-FCM-1900051). The briefing linked the objectives of the educational content to sales of Ferinject with statements such as:

- Once a customer believes in the value of IV iron for ID HF patients, this is the point at which you switch to using the Ferinject branded sales aid and continue to differentiate & promote the unique benefits of Ferinject for HF patients.'
- As market leaders it is our job to grow the IV iron market to allow more patients to benefit from IV iron; and Ferinject in particular.'

In addition, the sales aid (ref UK-FCM-1800049) to which this briefing related to included sections that were almost identical to those on the website at issue in this case, as well as promotional information in relation to Ferinject. Vifor submitted that whilst it did not consider that the sales aid as a stand-alone item was inappropriate, it did consider that the website at issue in this case, if intended as a non-promotional website, should not contain imagery identical to that in a promotional item.

Vifor submitted that with the above in mind there was a link between the website at issue in this case and a promotional item. Vifor were investigating the circumstances in which these

additional documents were approved and submitted that it would inform the PMCPA of the result of this in due course.

PANEL RULING

The Panel was concerned that Vifor had not provided all the relevant information in its initial response. However, the additional information was provided prior to the Panel's consideration of the case. The company had not provided the results of its investigation at the time the Panel considered the case.

The Panel noted Vifor's submission that the ivironheart.co.uk website as a stand-alone item was a non-promotional, medical educational website aimed at health professionals' to raise awareness of the role of iron in the heart, explain why heart failure patients might be iron deficient and to provide information on the consequences of iron deficiency for heart failure patients. It included reference to the treatment (both oral and intravenous) of iron deficiency in heart failure noting that a commonly used treatment, oral iron, was considered to be of limited benefit in heart failure (Lewis *et al* 2017).

The Panel noted that Clause 1.2 defined promotion as any activity undertaken by a pharmaceutical company or with its authority which promoted the administration, consumption, prescription, purchase, recommendation, sale, supply or use of its medicines.

The Panel noted that it appeared from information available at the time the complaint was received that when clicking on the link to the website provided by the complainant, the opening page of the website included a 'pop up'. This stated 'This site is intended for healthcare professionals treating patients with iron deficiency in chronic heart failure' and gave the reader the option of selecting 'I am a healthcare professional' or 'I am not a healthcare professional'.

The Panel noted that the first page of the website stated 'Because performance matters to your patients' followed by 'The role of iron and the impact of IV iron therapy for patients with heart failure and iron deficiency' below the Vifor Pharma logo. The page also included an image which appeared to be an engine in the shape of a real heart. The website referred to the role of iron in relation to energy production and contractility as well as the impact of iron deficiency particularly in heart failure and that the use of oral iron to treat iron deficiency in heart failure patients was not supported. It highlighted the potential issues with regard to using oral iron before discussing the clinical benefits of IV iron in this group of patients. In the Panel's view the imagery and claims for IV iron and statements about oral iron appeared to be of the type generally associated with promotion. The Panel considered that the content of the Vifor website, including the claims for IV iron and the reasons not to use oral iron was promotional for Vifor's IV iron products.

The Panel further noted Vifor's submission that health professionals were told about the website in a number of different ways including in a leavepiece used by representatives. The Panel had no detailed information in this regard.

The Panel disagreed with Vifor's submission that the reference to IV irons generally on the website was not a reference, either direct or indirect, to any specific medicine. There were references to specific medicines in the material, these being oral and IV treatments for iron deficiency. The Panel also disagreed with Vifor's submission that the main focus of the website was to emphasise the role of iron in the heart and the importance of treating iron deficiency in

heart failure patients, rather than specifically the use of IV iron in heart failure. The Panel also noted that it was an accepted principle under the Code that it was possible for material to promote a medicine without mentioning that medicine by name. In the Panel's view the website promoted IV iron and Vifor marketed two IV iron preparations, namely Ferinject and Venofer. In the Panel's view, noting its comments above, the website could not be considered anything other than promotional for those medicines.

The Panel then went on to consider the matter in relation to Vifor's subsequent submission that it had discovered that there was a link between the ivironheart.co.uk website and a promotional item, Vifor's global cardiology awareness campaign sales aid (ref UK-FCM-1800049) which included promotional information in relation to Ferinject. The briefing material for this sales aid (ref UK-FCM-1900051) gave background on the 'Cardiology Awareness Campaign' and referred to the purpose of the 'unbranded disease awareness campaign' as aiming to increase the number of iron deficient heart failure patients treated with IV iron, decrease the number inappropriately treated with oral iron and drive awareness of the European Society of Cardiology (ESC) diagnostic criteria for treating patients. The briefing material for the sales aid stated that the desired outcome to achieve for certain health professionals (evidence followers) was to acknowledge that Ferinject was the only iron therapy recommended by the ESC 2016 Heart Failure Guidelines and treat their patients accordingly. Representatives were instructed to switch to using the Ferinject branded sales aid once a customer believed in the value of IV iron for iron deficient heart failure patients '... and continue to differentiate and promote the unique benefits of Ferinject for heart failure patients'. The Panel noted that the ivironheart.co.uk website which contained imagery and content identical to that within the sales aid (UK-FCM-1800049) as acknowledged by Vifor appeared to be part of Vifor's campaign to promote Ferinject.

The Panel noted that the ivironheart.co.uk website did not include Ferinject or Venofer prescribing information nor did it include a clear and prominent statement as to where the prescribing information could be found. The Panel therefore ruled a breach of Clauses 4.1 and 4.6.

The Panel noted that the website did not include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [web address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]' as required by Clause 4.9. The Panel therefore ruled a breach of that clause.

The Panel noted that the website had not been certified for promotional use and thus ruled a breach of Clause 14.1.

The Panel noted that there was no allegation or details about what health professionals were told about the website when being directed to it either by the representatives handing out the leaflet or by some other means. The Panel noted that the allegation before it was that the website itself constituted disguised promotion. The Panel noted its comments above and did not consider that the Vifor website was disguised promotion; it was clearly promotional. The Panel therefore ruled no breach of Clause 12.1.

The Panel noted Vifor's submission that the website should contain more comprehensive information about both oral and IV irons and the website had been deactivated in order to address this. The Panel noted its comment above with regard to the content of the website in

relation to the limitations of oral iron and the clinical benefits of IV iron. The Panel did not consider that the website was sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicines and a breach of Clause 7.2 was ruled. The Panel further considered that the comparison between oral and IV iron portrayed by the website was misleading as alleged and a breach of Clause 7.3 was ruled.

The Panel was concerned to note that Vifor had failed to recognise that the ivironheart.co.uk website promoted its two products Ferinject and Venofer. The Panel was further concerned that this had not been picked up in relation to the Cardiology Awareness Campaign Sales Aid (UK-FCM-1800049) considering the link between the website and the sales aid and its associated briefing material. The same signatory had certified the three pieces ie the Cardiology Awareness Campaign Sales Aid, its associated briefing and the ivironheart.co.uk website. The Panel considered that Vifor had failed to maintain high standards and a breach of Clause 9.1 was ruled.

The Panel noted that the complainant had raised concerns about an employee and referred to him/her pushing through concepts without understanding the principles of the Code which led to pressure on the signatories. The Panel noted that the complainant bore the burden of proof and had not provided evidence to establish his/her complaint on the balance of probabilities in this regard. The Panel therefore ruled no breach of Clause 9.1.

It appeared that Vifor might have confused a non-promotional disease awareness campaign, which was usually aimed at members of the public rather than health professionals, with a promotional campaign for Ferinject. Further it appeared that Vifor staff had not fully understood the materials, their links to each other and the impact of relevant Code requirements.

Noting its comments and rulings above, the Panel considered that Vifor had brought discredit upon, and reduced confidence in, the industry and a breach of Clause 2 was ruled.

Complaint received **22 January 2020**

Case completed **27 July 2020**