CASE AUTH/3303/1/20

ANONYMOUS COMPLAINANT v VIFOR

Ferinject Website

An anonymous, contactable individual complained about the Vifor Pharma UK website for Ferinject (ferric carboxymaltrose) (ferinject.co.uk, ref UK-FCM-1900320, September 2019). Ferinject was indicated for the treatment of iron deficiency when oral iron preparations were ineffective or could not be used.

The complainant alleged that there were several problems with the Ferinject website which stemmed from a lack of understanding of the core principles of the Code and not using medical signatory input.

The homepage of the website which was intended for health professionals who treated iron deficiency and iron deficiency anaemia contained the brand logo and an indication which made the page promotional and therefore should have had prescribing information available for health professionals. In addition, there should have been an adverse event reporting box. If the page was viewed as non-promotional (difficult to do so as the branded colour logo and indication gave promotional texture), then the adverse event box for patients was also missing and the page promoted to the public.

If visitors to the website stated that they were a health professional and clicked through to ferinject.co.uk/health-professional, the adverse events box was missing yet again and none of the pages for health professionals had adverse event reporting wording either.

A claim that 'Ferinject is easy to administer' could not be substantiated and was not accurate as the IV infusion required a large number of steps including dilution and choosing appropriate concentrations which made it complex to administer in addition to the close monitoring of the patient needed. Further, the administration times for different doses were different and so it was not straightforward. The complainant alleged that the claim was misleading and not accurate.

One of the pages claimed 'Simplified dosing and administration for all patients with Ferinject'. However, the summary of product characteristics (SPC) stated that 'The use of Ferinject has not been studied in children, and therefore is not recommended in children under 14 years'. The age restriction in the Ferinject licence was not listed anywhere on the page and so if readers only read this page it was a misleading claim.

The complainant noted that none of the patient pages had adverse event reporting statements. The only page which mentioned side effects for patients (ferinject.co.uk/patient/side-effects), stated 'If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed on the Patient Information Leaflet'. However, this was not consistent with the wording required.

The detailed response from Vifor is given below.

The Panel noted that the landing page of the Ferinject website included the Ferinject logo in the top right hand corner and was headed 'Welcome to Ferinject.co.uk' followed by 'This website is intended for healthcare professionals who treat iron deficiency and iron deficiency anaemia in adults or patients who have been prescribed this medication. Please select one of the following:'. The options given were 'I am a healthcare professional'; 'I am a patient who has been prescribed Ferinject' and 'I am neither of the above'.

The Panel noted that the open access website landing page, whilst not aimed at the public would potentially be seen by a broad audience including members of the public. The Panel noted that the landing page was a mechanism to direct three potential audiences (health professionals, patients taking Ferinject and the public) to information relevant to each audience. This was not unacceptable so long as the webpage complied with the Code and was suitable for the general public. The Panel noted that landing page included the branded Ferinject logo and mentioned treatment in iron deficiency and iron deficiency anaemia in adults. In the Panel's view, the landing page promoted a prescription-only medicine to the public and a breach was ruled.

The Panel noted that a landing page which was openly accessible to the general public and therefore not limited to a health professional audience should not be promotional and therefore prescribing information and other obligatory information which must be provided when promoting to health professionals was not required. The Panel therefore ruled no breaches of the Code.

Similarly, noting its comments above with regard to the landing page being a mechanism to direct three potential audiences including patients taking Ferinject to information relevant to them, the Panel did not consider that the landing page was aimed specifically at patients prescribed Ferinject and therefore information for patients about how to report adverse events was not relevant and no breach was ruled in relation to the landing page.

The Panel noted that the section of the website intended for patients prescribed Ferinject (Ferinject website – Patient – iron Deficiency page (ref UK-FCM-1900009) included a tab entitled 'Side Effects' at the top of the homepage which took readers, via a direct single click, to a page (Ferinject website – Patient – Side Effects page (ref UK-FCM-1900018) that included, under the heading 'Reporting side effects in the UK', a statement with regard to how to report adverse events in line with the requirements of the Code. The Panel therefore ruled no breach. The Panel noted the complainant's concern that if visitors to the website stated that they were a health professional and clicked through to ferinject.co.uk/health-professional, the adverse events box was missing and none of the pages for health professionals included the adverse event reporting wording. The Panel noted that the top of the homepage of the health professional section of the website included a number of tabs including one titled 'Prescribing Information'. The Panel noted that that page included that: Adverse events should be reported followed by reporting forms and information can be found at www.mhra.gov.uk/yellowcard (and the corresponding Irish details) and that adverse events should also be reported to Vifor Pharma UK Ltd with a telephone number provided. As the required information about reporting adverse events was included within the prescribing information tab, the Panel ruled no breach of the Code.

The Panel noted the complainant's allegations that the claim 'Ferinject is easy to administer' (on ferinject.co.uk/healthcare-professional (ref UK-FCM-1800089, January 2019)) was misleading and could not be substantiated. The Panel noted Vifor's submission that the claim was in fact that Ferinject was 'simple to administer' and in that regard Vifor noted that a patient's dose of iron could be calculated in one of two ways: using the Ganzoni formula or a simplified dosing table and the dosing of Ferinject according to its SPC was based on the simplified table exclusively. The Panel considered that the calculation of an iron dose was different to the administration of a dose. In responding to this allegation Vifor only referred to the calculation of the dose and not its administration.

According to its SPC, Ferinject should only be administered when staff trained to evaluate and manage anaphylactic reactions were immediately available, in an environment where full resuscitation facilities could be assured and the that the patient should be observed for adverse effects for at last 30 minutes following each Ferinject administration. The posology of Ferinject followed a stepwise approach including: (1) determination of the individual iron need (the dosing of Ferinject according to its SPC was based on the simplified table exclusively); (2) calculation and administration of the iron dose(s); and (3) post-iron repletion assessments. Ferinject could be administered by three methods via the intravenous route: injection, infusion or during a haemodialysis session undiluted directly into the venous limb of the dialyser. When Ferinject was to be administered by intravenous injection an undiluted solution could be used and there were different administration rates based on the volume of Ferinject required and the equivalent iron dose. If using intravenous infusion Ferinject must be diluted according to a dilution plan as set out in the SPC which included a minimum administration time depending on the volume of Ferinject required and the equivalent iron dose and the amount of sterile 0.9% m/V sodium chloride used for dilution. The Panel noted that whilst the dosing of Ferinject within the context of IV iron therapy based on the simplified table might be simple compared to alternative IV irons which used the Ganzoni formula, it appeared that the administration of Ferinject was not simple as implied by the claim which the Panel considered was misleading and could not be substantiated. The Panel therefore ruled breaches of the Code.

The Panel then considered the complainant's allegation that the claim 'Simplified dosing and administration for all patients with Ferinject' (Ferinject.co.uk/healthcare-professional (ref-UK-FCM-1900275, August 2019)) misleadingly implied that Ferinject could be used in patients under 14 years whereas the SPC stated that 'The use of Ferinject has not been studied in children, and therefore is not recommended in children under 14 years' and this was not included anywhere on the page.

The Panel noted that according to Vifor there were two ways that readers could access the 'Administration' page containing the claim in question, both via the health professional homepage. Firstly, via the 'Administration' tab at the top of the homepage and secondly, via a link for more information beneath the claims 'SIMPLIFIED DOSING FOR ALL PATIENTS' and 'LICENSED FOR AGES 14 YEARS AND OVER' which appeared within a section on the homepage headed 'Why use Ferinject?' along with four other claims for the product. All six claims were of equal prominence.

The Panel noted Vifor's submission that the health professional homepage was accessed after selecting 'I am a healthcare professional' from the website landing page which clarified that the health professional section of the website was intended for health professionals 'who treat iron deficiency and iron deficiency anaemia in adults…' (emphasis added). The Panel further noted that if readers had accessed the Administration page via the 'Why use Ferinject?' section of the homepage they would have seen that Ferinject was only licensed for ages 14 and over. The Panel did not consider that the claim 'Simplified dosing and administration for all patients with Ferinject' implied that Ferinject could be used in patients under 14 years as alleged and no breaches of the Code were ruled.

The Code required that promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements. The Panel noted its rulings of breaches of the Code in relation to material for health professionals and material for the public as set out above and therefore ruled breaches of the Code.

The Panel noted its comments and rulings above and 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 an employee not being a signatory and not understanding the principles of the Code. The Panel noted Vifor's submission that the materials had been certified by its signatories and that the employee in question had played no role in the approval of the material at issue in this case. The Panel noted that the complainant bore the burden of proof and not provided evidence to establish his/her complaint in this regard on the balance of probabilities. The Panel therefore ruled no breach of Clause 9.1 in relation to this allegation.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 and ruled no breach accordingly.

An anonymous, contactable individual complained about the Vifor Pharma UK website for Ferinject (ferric carboxymaltrose) (ferinject.co.uk, ref UK-FCM-1900320, September 2019). 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 there were several problems with the Ferinject website which stemmed from a lack of understanding of the core principles of the Code and not using medical signatory input.

The homepage of the website which was intended for health professionals who treated iron deficiency and iron deficiency anaemia contained the brand logo and an indication which made the page promotional and therefore should have had prescribing information available for health professionals. In addition, there should have been an adverse event reporting box. Both were missing in breach of Clauses 4.1 and 4.9.

If the page was viewed as non-promotional (difficult to do so as the branded colour logo and indication gave promotional texture), then the adverse event box for patients was also missing in breach of Clause 26.3. Furthermore, by having an indication and logo and being promotional in nature, it was promoting to the public in breach of Clause 26.1.

If visitors to the website stated that they were a health professional and clicked through to ferinject.co.uk/health-professional, the adverse events box was missing yet again in breach of Clause 4.9 which was very worrying given that Ferinject was a black triangle product. None of the pages for health professionals had adverse event reporting wording either.

On ferinject.co.uk/healthcare-professional (ref UK-FCM-1800089, January 2019), the claim that 'Ferinject is easy to administer' could not be substantiated and was not accurate as the IV infusion required a large number of steps including dilution and choosing appropriate concentrations which made it complex to administer in addition to the close monitoring of the patient needed. Further, the administration times for different doses were different and so it was not straightforward. The complainant alleged a breach of Clause 7.2 and 7.4 as the claim was misleading and not accurate.

Ferinject.co.uk/healthcare-professional (ref-UK-FCM-1900275, August 2019) stated that there was 'Simplified dosing and administration for **all** patients with Ferinject'. However, the summary of product characteristics (SPC) stated that 'The use of Ferinject has not been studied in children, and therefore is not recommended in children under 14 years'. The age restriction in the Ferinject licence was not listed anywhere on the page and so if readers only read this page it was a misleading claim as they could assume that Ferinject could be used in patients under 14 years. The complainant alleged further breaches of Clause 7.2 and 7.4.

The complainant noted that none of the patient pages had adverse event reporting statements in breach of Clause 26.3 (eg ferinject.co.uk/patient/ida-management). The only page which mentioned side effects for patients (ferinject.co.uk/patient/side-effects), stated 'If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed on the Patient Information Leaflet'. However, this was not consistent with the wording required by Clause 26.3.

As there were so many core issues with the website, the complainant further alleged breaches of Clauses 28.1, 28.3 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.

RESPONSE

Vifor noted that the complainant's concerns about the Ferinject website related to four topics as follows.

1 Website landing page

Vifor explained that the website (ferinject.co.uk) had two objectives; to provide information to patients prescribed Ferinject and to provide clinical information to health professionals who sought such data about Ferinject. The two sections of the website were clearly separated and the intended audience was evident from the outset. The site went live on 27 September 2019

and was promoted to health professionals by means of the web address which appeared on printed materials, eg leavepieces, and a renal email campaign sent as a one-off on 18 October. Patients prescribed Ferinject were made aware of the site by a patient leaflet handed to them by their health professional as part of a post-prescription service.

Vifor submitted that whilst it could be argued that the inclusion of both product name and indication on the website landing page rendered the web page promotional, the intention of the landing page was to direct readers to the relevant section of the website, depending on whether they were a patient taking the medicine or a health professional seeking information about the medicine. In order to be able to direct the reader effectively it was necessary to refer to both the product name and the indication.

Vifor noted that Case AUTH/3166//2/19 indicated that the intention of an item or activity was important when considering its nature, and given the objective of the website identified above, Vifor denied that the landing page was promotional. Thus obligatory information such as a link to prescribing information or adverse event reporting wording was not required and it denied a breach of Clauses 4.1 and 4.9.

Similarly, Vifor submitted that the page did not promote Ferinject to the public. The target audience of the website was clearly indicated on the landing page; in accordance with guidance from The Medicines and Healthcare products Regulatory Agency (MHRA), if a reader identified themselves as neither a health professional nor a patient prescribed Ferinject, they were directed away from the website to the Vifor company website. The company denied a breach of Clause 26.1.

Vifor noted the complainant's speculation that if the landing page was not considered promotional then it should be considered material intended for patients taking Ferinject and thus required certain adverse event reporting wording. Vifor reiterated the intent of the landing page; it was not to inform a patient about a medicine that they were taking, but to direct them to where such information could be found, thus adverse event reporting wording was not required on the landing page itself and it denied a breach of Clause 26.3.

2 Obligatory information

Vifor noted that the complainant had stated that on entering the health professional section of the website the adverse event box was missing. By 'adverse event box', Vifor assumed that the complainant meant the obligatory adverse event reporting wording required for all promotional material.

Vifor stated that a very clearly labelled link at the top of the health professional home page, 'Prescribing Information', took readers, via a direct single click, to the prescribing information and to the very prominent wording in relation to adverse event reporting should health professionals see any side effects in their patients. It was common industry practice to have such wording in the same location as other obligatory information such as the prescribing information. Vifor denied a breach of Clause 4.9.

Vifor noted that the complainant also claimed that the section of the website intended for patients prescribed Ferinject did not contain 'adverse event reporting statements', excepting on one page which contained a statement that did not reflect the wording required in Clause 26.3.

Vifor stated that this section of the website was intended for patients prescribed Ferinject and thus Clause 26.3 was relevant. There was a clearly labelled link at the top of the patient home page that stated 'Side Effects' and took readers, via a direct single click, to a page that contained, under the heading 'Reporting side effects in the UK', the following statement:

> 'If you get side effects, talk to your doctor or nurse. This includes any possible side effects not listed in the Patient Information Leaflet.
>
> Ferinject is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get to: United Kingdom, Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store
>
> Side effects should also be reported to Vifor Pharma UK Ltd. Tel:+44 1276 853633 or Email: medicalinfo_UK@viforpharma.com.'

Vifor contended that this was the most obvious place to put the statement required under Clause 26.3, and also noted that this clause included suggested, not prescriptive, wording for the statement. Vifor submitted that the wording contained in the section of the website at issue complied with the requirement of Clause 26.3 and it denied any breach in that regard.

3 Administration of and patient population for Ferinject

The complainant alleged that the claim on the page intended for health professionals that Ferinject was 'easy to administer' was misleading and not accurate.

The claim on the page was in fact that Ferinject was 'simple to administer' and in that regard Vifor noted that a patient's dose of iron could be calculated in one of two ways:

- Ganzoni formula use – eg for Venofer, Diafer, Cosmofer and Monofer (except where simplified dosing was possible).
- Simplified dosing table/grid – eg for Ferinject for all patients requiring treatment and Monofer for a defined group of patients requiring treatment.

Within the context of dosing based on the patient's iron need, body weight and haemoglobin levels, the simplified dosing grid contained in the Ferinject summary of product characteristics (SPC), and referred to in relation to study FER-IBD-07-COR in section 5.1 (gastroenterology), provided health professionals with posology guidance that was simple in the context of IV iron treatment, especially so when compared with the alternative Ganzoni formula calculation listed below:

$$\underset{\text{[mg iron]}}{\text{Iron need}} = \underset{\text{[kg]}}{\text{Body weight}^{(A)}} \times (\underset{\text{[g/dl]}}{\text{TargetHb}^{(E)}} - \text{Actual Hb})^{(B)} \times 2.4^{(C)} + \underset{\text{[mg iron]}}{\text{Iron for iron stores}^{(D)}}$$

Vifor did not accept that describing the administration of Ferinject as simple was either inaccurate or unsubstantiable, and therefore denied a breach of Clauses 7.2 and 7.4 in that regard.

Vifor noted that the complainant also alleged that the claim 'Simplified dosing and administration for all patients with Ferinject' implied that Ferinject could be used in patients under the age of

14. However, readers accessed this page via the health professional home page, via a link under the claim 'Simplified Dosing For All Patients' which appeared in the same location on the web page as several other claims, all with equal prominence, one of which was 'Licensed For Ages 14 Years and Over'. Vifor thus denied that there was any inference that the medicine could be used in patients under the age of 14. The claim was not misleading and could be substantiated and it refuted any breach of Clauses 7.2 and 7.4 in that regard.

Given all of the above, Vifor submitted that the promotional material in the health professional section of the Ferinject website was appropriate and complied with relevant requirements of the Code, consistent with Clause 28.1 and it denied any breach of that clause. In addition, the intended audience for the website did not include the public, therefore Clause 28.3 was not relevant. The company concluded that there thus had been no breach of Clauses 9.1 or 2.

4 Qualifications of a Vifor employee

Vifor noted that the complainant had made the tenuous assumption regarding the employee. Vifor gave further details including that his/her academic qualifications and extensive experience provided ample justification for the role he/she was currently in 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 the qualifications of its signatories who had certified the website.

In response to a request for further information Vifor provided a copy of the version of the prescribing information that a reader of the website at issue would have viewed if they clicked on the 'Prescribing Information' link at the time that the complaint was received (January 2020).

Vifor submitted that the claim 'Simplified dosing for all patients' appeared on the health professional homepage of the website at issue. The same webpage also included, in the same location, the claim 'Licensed for ages 14 years and over' alongside 4 other claims. Vifor submitted that if the health professional clicked on the 'More information' link underneath either claim, or clicked on the 'Administration' tab at the top of the homepage, they were taken to the same page ('the Administration page') which contained the claim at issue 'Simplified dosing and administration for all patients with Ferinject'.

Vifor submitted that the health professional homepage was accessed after selecting 'I am a healthcare professional' from the website landing page. This landing page clarified that the health professional section of the website was intended for health professionals 'who treat iron deficiency and iron deficiency anaemia in **adults**…' (emphasis added). Thus, whichever route a health professional took to access the Administration page, which contained the claim at issue, Vifor considered that the patient population for which Ferinject was licensed to treat was clear.

PANEL RULING

The Panel noted Vifor's submission that the website (ferinject.co.uk) had two objectives; to provide information to patients prescribed Ferinject and to provide clinical information to health professionals who sought such data about Ferinject.

The Panel noted that the landing page of the Ferinject website (ferinject.co.uk) included the Ferinject logo in the top right hand corner and was headed 'Welcome to Ferinject.co.uk' followed by 'This website is intended for healthcare professionals who treat iron deficiency and iron deficiency anaemia in adults or patients who have been prescribed this medication. Please select one of the following:'. The options given were 'I am a healthcare professional'; 'I am a patient who has been prescribed Ferinject' and 'I am neither of the above'. According to Vifor if a reader identified themselves as neither a health professional nor a patient prescribed Ferinject, they were directed away from the website to the Vifor company website.

The Panel noted that according to Vifor the website was promoted to health professionals by means of the web address which appeared on printed materials. Patients prescribed Ferinject were made aware of the site by a patient leaflet handed to them by their health professional as part of a post-prescription service.

The Panel noted that the open access website landing page, whilst not aimed at the public would potentially be seen by a broad audience including members of the public. The Panel noted that the landing page was a mechanism to direct three potential audiences (health professionals, patients taking Ferinject and the public) to information relevant to each audience. This was not unacceptable so long as the webpage complied with the Code and was suitable for the general public. The Panel noted that landing page included the branded Ferinject logo and mentioned treatment in iron deficiency and iron deficiency anaemia in adults. In the Panel's view, the homepage was therefore promotional. The Panel disagreed with Vifor's submission that in order to be able to direct the reader effectively it was necessary to refer to both the product name and the indication. In the Panel's view, the landing page promoted a prescription-only medicine to the public and a breach of Clause 26.1 was ruled.

The Panel noted its ruling above that the landing page promoted a prescription only medicine and for a health professional audience prescribing information and other obligatory information would be needed. The Panel noted however that a landing page which was openly accessible to the general public and therefore not limited to a health professional audience should not be promotional and therefore prescribing information and other obligatory information which must be provided when promoting to health professionals was not required. The Panel therefore ruled no breach of Clauses 4.1 and 4.9.

Similarly, noting its comments above with regard to the landing page being a mechanism to direct three potential audiences including patients taking Ferinject to information relevant to them, the Panel did not consider that the landing page was aimed specifically at patients prescribed Ferinject and therefore the requirement of Clause 26.3 was not relevant and no breach was ruled in relation to the landing page.

The Panel noted that Clause 26.3 required that any material which related to a medicine and which is intended for patients taking that medicine must include the statement below or a similar one: 'Reporting of side effects' If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in the package leaflet. You can also report side effects directly via the Yellow Card Scheme at [a web address which links directly to the MHRA Yellow Card site]. By reporting side effects you can help provide more information on the safety of this medicine'. The Panel noted that the section of the website intended for patients prescribed Ferinject (Ferinject website – Patient – iron Deficiency page (ref UK-FCM-1900009) included a tab entitled 'Side Effects' at the top of the homepage which took readers, via a direct single click, to a page (Ferinject website – Patient – Side Effects page (ref UK-FCM-

1900018) that included, under the heading 'Reporting side effects in the UK', a statement with regard to how to report adverse events in line with Clause 26.3. The Panel therefore ruled no breach of Clause 26.3.The Panel noted the complainant's concern that if visitors to the website stated that they were a health professional and clicked through to ferinject.co.uk/health-professional, the adverse events box was missing and none of the pages for health professionals included the adverse event reporting wording. The Panel noted that the top of the homepage of the health professional section of the website included a number of tabs including one titled 'Prescribing Information'. The Panel noted that that page included that: Adverse events should be reported followed by reporting forms and information can be found at www.mhra.gov.uk/yellowcard (and the corresponding Irish details) and that adverse events should also be reported to Vifor Pharma UK Ltd with a telephone number provided. As the required information about reporting adverse events was included within the prescribing information tab, the Panel ruled no breach of Clause 4.9.

The Panel noted the complainant's allegations that the claim 'Ferinject is easy to administer' (on ferinject.co.uk/healthcare-professional (ref UK-FCM-1800089, January 2019)) was misleading and could not be substantiated as the IV infusion required a large number of steps including dilution and choosing appropriate concentrations which made it complex to administer in addition to the close monitoring of the patient needed. Further, the administration times for the various doses were different and so it was not straightforward. The Panel noted Vifor's submission that the claim was in fact that Ferinject was 'simple to administer' and in that regard Vifor noted that a patient's dose of iron could be calculated in one of two ways: using the Ganzoni formula or a simplified dosing table and the dosing of Ferinject according to its SPC was based on the simplified table exclusively. The Panel considered that the calculation of an iron dose was different to the administration of a dose. In responding to this allegation Vifor only referred to the calculation of the dose and not its administration.

The Panel noted the complainant had incorrectly referred to the claim as 'easy to administer' when the claim in full was that 'Ferinject is a simple to administer, well-tolerated treatment option for repletion of iron stores when oral iron is ineffective or cannot be used'.

According to its SPC, Ferinject should only be administered when staff trained to evaluate and manage anaphylactic reactions were immediately available, in an environment where full resuscitation facilities could be assured and the that the patient should be observed for adverse effects for at last 30 minutes following each Ferinject administration. The posology of Ferinject followed a stepwise approach including: (1) determination of the individual iron need (the dosing of Ferinject according to its SPC was based on the simplified table exclusively); (2) calculation and administration of the iron dose(s); and (3) post-iron repletion assessments. Ferinject could be administered by three methods via the intravenous route: injection, infusion or during a haemodialysis session undiluted directly into the venous limb of the dialyser. When Ferinject was to be administered by intravenous injection an undiluted solution could be used and there were different administration rates based on the volume of Ferinject required and the equivalent iron dose. If using intravenous infusion Ferinject must be diluted according to a dilution plan as set out in the SPC which included a minimum administration time depending on the volume of Ferinject required and the equivalent iron dose and the amount of sterile 0.9% m/V sodium chloride used for dilution. The Panel noted that whilst the dosing of Ferinject within the context of IV iron therapy based on the simplified table might be simple compared to alternative IV irons which used the Ganzoni formula, it appeared that the administration of Ferinject was not simple as implied by the claim which the Panel considered was misleading and could not be substantiated. The Panel therefore ruled a breach of Clauses 7.2 and 7.4.

The Panel then considered the complainant's allegation that the claim 'Simplified dosing and administration for **all** patients with Ferinject' (Ferinject.co.uk/healthcare-professional (ref-UK-FCM-1900275, August 2019)) misleadingly implied that Ferinject could be used in patients under 14 years whereas the SPC stated that 'The use of Ferinject has not been studied in children, and therefore is not recommended in children under 14 years' and this was not included anywhere on the page.

The Panel noted that Section 4.2 of the SPC stated that the use of Ferinject had not been studied in children and therefore it was not recommended in children under 14 years.

The Panel noted that according to Vifor there were two ways that readers could access the 'Administration' page containing the claim in question, both via the health professional homepage. Firstly, via the 'Administration' tab at the top of the homepage and secondly, via a link for more information beneath the claims 'SIMPLIFIED DOSING FOR ALL PATIENTS' and 'LICENSED FOR AGES 14 YEARS AND OVER' which appeared within a section on the homepage headed 'Why use Ferinject?' along with four other claims for the product. All six claims were of equal prominence.

The Panel noted Vifor's submission that the health professional homepage was accessed after selecting 'I am a healthcare professional' from the website landing page which clarified that the health professional section of the website was intended for health professionals 'who treat iron deficiency and iron deficiency anaemia in **adults**…' (emphasis added). The Panel further noted that if readers had accessed the Administration page via the 'Why use Ferinject?' section of the homepage they would have seen that Ferinject was only licensed for ages 14 and over. The Panel did not consider that the claim 'Simplified dosing and administration for **all** patients with Ferinject' implied that Ferinject could be used in patients under 14 years as alleged and no breach of Clauses 7.2 and 7.4 were ruled.

Clause 28.1 required that promotional material about prescription only medicines directed to a UK audience which is provided on the Internet must comply with all relevant requirements of the Code. Clause 28.3 required that information about medicines covered by Clauses 28.1 and 28.2 which was provided on the Internet and which was intended for members of the public must comply with Clause 26.2. The Panel noted its rulings of breaches of the Code in relation to material for health professionals and material for the public as set out above and therefore ruled a breach of Clauses 28.1 and 28.3.

The Panel noted its comments and rulings above and 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 not being a signatory and not understanding the principles of the Code. The Panel noted Vifor's submission that the materials had been certified by its signatories and that the employee in question had played no role in the approval of the material at issue in this case. The Panel noted that the complainant bore the burden of proof and not provided evidence to establish his/her complaint in this regard on the balance of probabilities. The Panel therefore ruled no breach of Clause 9.1 in relation to this allegation.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel did not consider that the particular circumstances of this case warranted a ruling of a breach of Clause 2 and ruled no breach accordingly.

Complaint received **23 January 2020**

Case completed **3 August 2020**