Medicines Australia

Better health through research & innovation

COMPLAINT OUTCOME

1177 - Promotional material related to MONOFER

DETERMINATIONS OF THE MEDICINES AUSTRALIA CODE OF CONDUCT COMMITTEE

The administration of the Code is supervised by the Code of Conduct Committee. The Code of Conduct Committee has the power to make a determination as to a breach of the Code and impose sanctions. The right of appeal is available to both the Complainant and Subject Company. An appeal is heard by the Appeals Committee which has the power to confirm or overturn the decision and to amend or remove any sanctions.

The decisions of the Code of Conduct and Appeals Committees are relevant to the date of publication of the materials subject to complaint and approved Product Information (PI) at that time. A complaint is not deemed finalised until both parties have advised Medicines Australia that they will not appeal the outcome of the Code of Conduct Committee decision (following circulation of the Committee's Reasons) or, in the case of an appeal, the Appeals Committee Reasons have been provided to both parties.

This report is an extract of the 'Reasons for Decision' provided by the Code Committee. The complaint was heard by the Code Committee on 17th February 2025.

CONTACT US

17 Denison Street, Deakin, ACT 2600
Phone: 02 6147 6500
Email the Ethics & Compliance Team

DOWNLOAD THE CODE

The Code of Conduct and all associated materials are available on the Medicines Australia website.

COMPLAINT 1177 Promotional material related to MONOFER

SUBJECT COMPANY	PRODUCT	COMPLAINANT
A. Menarini	MONOFER (Ferric derisomaltose)	CSL Seqirus

COMPLAINT

CSL considered that Menarini adopted a promotional strategy, the effect of which was to disparage CSL's product Ferinject through misleading and unbalanced content. They alleged this strategy was to repeatedly report biochemical hypophosphataemia incidence associated with Ferinject, without any attempt to attach clinical significance or context.

This complaint centred on four items that were provided to healthcare professionals in 2024: 2 x leavepieces, 1 x advertorial (developed by Menarini) and 1 x poster (independently published).

The complainant objected to the manner in which the subject company presented hypophosphataemia and its potential complications as an outcome following Ferinject treatment. They claimed that data on the clinical significance of hypophosphataemia, or actual clinical outcomes seen after Ferinject treatment, was absent. The complainant took the view that the content misinformed and misled HCPs by exaggerating the risks of Ferinject, leaving them unable to make accurate and informed clinical decisions, and was therefore not aligned with the principles of Quality Use of Medicines. They also reported that the effect of the misleading messaging had introduced concern and confusion among healthcare professionals.

For clarity, the complainant agreed that hypophosphataemia had been reported following use of Ferinject and is an adverse effect in a subset of patients requiring clinical assessment. This was not in question. The complaint focused on the promotional material which they believed had the effect of creating a misleading picture of the comparative safety of their product (Ferinject), which in turn, had the potential to inappropriately influence prescribing and impact the quality use of medicines.

SECTIONS OF THE CODE (EDITION 19)

- **Overarching Principle 1**: All activities undertaken by Companies have the purpose of supporting the quality use of medicines.
- **Overarching Principle 3**: Companies are responsible for providing current, accurate, balanced, and scientifically valid information products to support their use.
- **Overarching Principle 4**: Information relevant to prescribing, in particular product and safety information, are clearly communicated in all promotional materials. Promotional materials are designed by Companies to not only create awareness of Therapeutic Goods Administration (TGA) approved medicines, but to support proper assessment of their risks and benefits.
- **Overarching Principle 6:** Companies' interactions with all stakeholders are at all times professional, consistent with all legislative requirements, and appropriate to the information needs of the respective audience.

SECTIONS OF THE CODE (EDITION 19) continued

- **Overarching Principle 8:** All promotional claims are consistent with the Australian Product Information document, including claims about competitor products, irrespective of the source on which the claim is based.
- **Overarching Principle 10:** All activities undertaken by Companies are clearly identified to their audience as a Company activity by the inclusion of the Company's name and city/town of the Company's Australian office.
- **Section 1:** Requirements for Promotional Claims Directed at Healthcare Professionals.
- **Section 1.1:** Substantiating Data.
- **Section 2:** Requirements For Material Directed To Healthcare Professionals.
- **Section 8:** Scientific Exchange with Healthcare Professionals

The Committee noted that in contemporary Australian general practice, Monofer and Ferinject are the only two intravenous iron infusion products in common use that treat iron deficiencies when oral iron preparations are ineffective or cannot be used.

RESPONSE TO THE COMPLAINT

Menarini defended their approach, noting their purpose was to inform healthcare professionals with the most current body of evidence and to promote awareness of the mechanism and incidence of hypophosphatemia following IV irons and in at-risk patients.

In addition, Menarini:

1. did not agree that this constituted comparative advertising. "Ferinject" was not referenced in the body of the Menarini Materials and any comparison was 'illusory'.
2. did not agree the Poster should be subject to the complaint because it was never reviewed or approved for use or distribution by Menarini staff.
3. maintained the statement from the Ferinject PI 'hypophosphataemia in most cases is transient' did not accurately reflect the emerging body of evidence and therefore should not be included in their messaging about hypophosphatemia.

Menarini asserted that they were not disparaging Ferinject but reporting a well-documented risk difference between the active ingredient in Ferinject, Ferric Carboxymaltose ('FCM') and Monofer to Australians. They confirmed their materials aligned with the Ferinject PI and that any allegation of causing unnecessary fear or confusion for healthcare professionals was unwarranted.

In their response, they counter-claimed that the complainant had abused the Code and that the complaint was frivolous and vexatious.

CODE COMMITTEE DECISIONS

Following its consideration of the complaint, the Code Committee concluded that breaches of the Code had occurred. Sanctions were applied by the Code Committee. The decisions of the Code Committee are tabled on page 3, and the reasons for the decisions of the Code Committee are on pages 6-9. The Committee determined the complaint was not vexatious or frivolous and therefore no breach of the Code had occurred in relation to 16.4.

Neither the Subject Company nor the Complainant appealed the decisions of the Code Committee.

CODE COMMITTEE DECISIONS

Area of the Code	Monofer Leavepiece 1 ("Reducing the risk of hypophosphatemia after IV iron")	Monofer Leavepiece 2 ("The importance of dose optimization in the treatment of iron deficiency in heart failure")	Monofer Advertorial ("IV iron deficiency-induced hypophosphataemia: an emerging concern")	Poster ("What's all the hype about? Iron induced hypophosphataemia")
Principle 1	**BREACH (unanimous)**	**BREACH (unanimous)**	**BREACH (unanimous)**	*The Committee did not make any findings as to whether the poster breached the Code.*
Principle 3	**BREACH (unanimous)**	**BREACH (unanimous)**	**BREACH (unanimous)**	*Not alleged*
Principle 4	*Not alleged*	*Not alleged*	*Not alleged*	*The Committee did not make any findings as to whether the poster breached the Code.*
Principle 6	*Not alleged*	*Not alleged*	*Not alleged*	
Principle 7	**BREACH (unanimous)**	**BREACH (unanimous)**	**BREACH (unanimous)**	
Principle 8	**BREACH (unanimous)**	**BREACH (unanimous)**	**BREACH (unanimous)**	
Principle 10	*Not alleged*	*Not alleged*	*Not alleged*	*The Committee did not adjudicate because it was not raised in ICD.*
Section 1	**BREACH (unanimous)**	**BREACH (unanimous)**	**BREACH (unanimous)**	*The Committee did not make any findings as to whether the poster breached the Code.*
Section 1.1	*The Committee did not adjudicate because it was not raised in ICD.*	*The Committee did not adjudicate because it was not raised in ICD.*	*The Committee did not adjudicate because it was not raised in ICD.*	
Section 2	*Not alleged*	*Not alleged*	*Not alleged*	
Section 8	*Not alleged*	*Not alleged*	*Not alleged*	

CONSIDERATION OF ICD, COMPLAINT ACCEPTANCE AND ABUSE OF THE CODE, AS ALLEGED BY THE SUBJECT COMPANY

- The Committee took the view that interactions between the companies were suboptimal, as demonstrated by a disagreement on the minutes of intercompany dialogue ('ICD').
- The Committee reflected that the ICD process provides an opportunity for companies to resolve their differences, an opportunity best realised when companies are open to exploring and testing potential solutions to address each other's concerns. Companies are encouraged to approach ICD with a clear focus on constructive resolution and communicating practical steps to address the issues raised.
- In their response to the complaint, the subject company outlined new allegations that were not raised in ICD. Where these related to alleged breaches and the complainant was not able to demonstrate that they were raised with the subject company through ICD, the Code Committee excluded these allegations from their adjudication. This is in keeping with the current approach that the Committee will only adjudicate on matters that have been raised satisfactorily during the intercompany dialogue process.
- In some instances, the subject company argued that elements of the complaint were 'new allegations' because they included language that had not appeared in the ICD material. The Committee took the view that these instances were largely restatements or elaborations, sometimes in different words, of matters that appeared to have been within the scope of the ICD. A complaint's progression, from its initial expression through the ICD process and eventually to Medicines Australia, does not necessarily require identical wording at each stage. The Committee considered that the substance of the complaint is what ultimately matters.
- As a result, the Committee confirmed that these matters as referenced above would not be dismissed as requested by the subject company. It noted that Medicines Australia is not mandated to adjudicate on the intricacies of ICD between companies. The Committee confirmed the approach taken by Medicines Australia was correct and appropriate.
- The subject company claimed that the complainant had breached Section 16.4 of the Code, which relates to complaints that are frivolous or vexatious.
- The Committee noted that a determination of this allegation could only be made in circumstances where the complainant had been afforded an opportunity to respond to it and therefore could only occur at a future meeting.
- The Committee therefore confined its consideration to the question of whether there was any plausible prospect (even an unlikely one) of the allegation being found to be justified. If it had so found, then it would have been appropriate for a response to be sought from the complainant and the allegation and response to be considered on a future date.
- In this case, the Committee unanimously determined that the complaint was not frivolous or vexatious or otherwise an abuse of the Code, particularly given that the breaches alleged were in fact found to have occurred.

CONSIDERATION OF THE POSTER

The fourth piece of material subject to the complaint ('the **poster**') was published independently of the subject company. The complainant alleged the poster was delivered to healthcare professionals by the subject company's sales representatives and should be considered as part of the promotional material subject to the complaint.

The subject company argued that the poster was not part of their materials because they were not published or approved by them.

The fundamental concern was:

- The subject company did not confirm whether the poster was delivered by their sales representatives, nor explain any further details about whether or how the poster was circulated, and
- In their complaint, the complainant did not provide sufficient evidence to demonstrate that the poster had in fact been distributed by the sales representatives of the subject company.

Notwithstanding this, the Committee ultimately formed the view that in the absence of clear evidence either way, it could not properly find that the poster had been distributed in the manner alleged by the complainant. The Committee therefore made no findings as to whether the poster breached the Code.

The Committee noted that in any event the subject company indicated that the poster would not be distributed by their staff in the future. Nonetheless, the Committee respected the decision of the complainant to withhold specific clinic details in order to protect the privacy and confidentiality of the clinics and healthcare individuals involved who had reported that the posters had been provided by staff of the subject company.

The Committee discussed the subject company's response to this specific allegation and expressed disappointment that the subject company:

- had not used intercompany dialogue to clarify whether the poster had been distributed by staff of the subject company or elaborate on the circumstances which may have contributed to this allegation being raised,
- took the view that the poster in question was not developed or approved for use by the subject company and was therefore not part of their Materials, implying they did not consider themselves accountable or responsible for unapproved materials distributed by their staff, and,
- undertook an internal investigation that, as described to the Code Committee, did not clarify whether the poster had in fact been distributed to practices by their staff but instead focused solely on whether the poster was developed or approved by the company (see point above).

Whilst the Committee refrained from adjudicating on the poster due to the points above, it reflected on the broader importance of accountability and transparency.

In particular, the Committee noted that, as a general proposition, material provided by a sales representative to a healthcare professional in support of promotional activity would be regarded as company promotional material, regardless of whether the material was developed or formally approved for use by the company.

CONSIDERATION OF THE COMPLAINT by the CODE COMMITTEE

- Hypophosphataemia has been reported following use of Ferinject and is an adverse effect in a subset of patients requiring clinical assessment. This is confirmed in the adverse events and precautions sections of the Ferinject PI as well as in literature, and this fact is not disputed by either company.
- The Committee considered that the core of the complaint related to the manner in which the subject company presented this side effect, and this was present in all three of the materials developed by the subject company.
- The Committee considered the subject company's assertion that the material aimed to raise awareness of the mechanism and incidence of hypophosphatemia following IV irons. The Committee accepted that the material would increase awareness of the risk of hypophosphataemia resulting from IV iron supplementation. However, it did so in a manner which, through emphasis and omission, also constituted a misleading comparison between Monofer and Ferinject.
- The Committee considered the subject company's assertion that the material is not comparative 'because Ferinject is not mentioned once in the Menarini Materials; but only the active ingredient, FCM.' Ferric carboxymaltose is marketed in Australia under the brand name Ferinject. Because Ferinject is commonly known as "ferric carboxymaltose" ("FCM"), and there are no other Australian products known by this active ingredient for this to be mistaken as anything other than Ferinject, the Committee rejected this argument. The Committee also noted that the material made repeated reference to the Ferinject PI on multiple occasions, though without expressly naming Ferinject PI.
- The Committee was therefore satisfied that material constituted comparative advertising. Highlighting the incidence of biochemical hypophosphataemia in a comparative setting serves the promotional purposes of the subject company because the incidence is significantly higher for patients using Ferinject.
- Comparative promotional material is permitted under the Code, so the fact the material was considered comparative, does not present any Code breach.
- Further, it was noted that any comparative statements or comparative material needs to be presented in a fair and just manner, and extra care must be taken to ensure that any comparison properly reflects the body of evidence and does not mislead by distortion, by undue emphasis or in any other way. All materials need to be current, accurate, balanced, and scientifically valid information on products to support their appropriate use.
- The Committee understood that the use of Ferinject is known to carry a risk of hypophosphataemia. This was not disputed by the complainant. However, it is also the case (and the PI confirms) that "in most cases [the hypophosphataemia] is transient and without clinical symptoms". The Committee took the view that the material lacked balance and accuracy by omission because it failed to communicate the normally transient and asymptomatic nature of hypophosphataemia caused by the use of Ferinject.
- The Committee observed that selective clinical studies were presented in a manner that suggested a direct association between the results, creating an implied narrative. Overall, this narrative did not allow the reader to be able to evaluate the validity of results, nor accurately understand the significance of the information being presented.

- Data was presented in a way that de-emphasised some important contextual information, such as differences in dose administration or the specific population studied and confounded the relationship between clinical and biochemical severity measures of hypophosphataemia. In doing so, it had the effect of overstating the significance and incidence of hypophosphataemia and was therefore likely to dissuade healthcare professionals from prescribing Ferinject beyond a balanced presentation of the risks.
- The Committee concluded this narrative permeated all three materials. The Committee agreed the material was misleading for the same reasons.
- The Committee also noted other elements of the material which added to the concern about lack of balance and misleadingness. For example, a picture of bones, together with the statement 'Hypophosphataemia may lead to bone demineralization' and 'Hypophosphatemia is a common but overlooked complication of FCM' would likely lead the reader to the inaccurate conclusion that bone demineralization complications with Ferinject are likely, frequent, or a predominant consideration in prescribing. In the context of the material—and the comparisons it included—the approach was too emphatic to be considered an acceptable means of promoting awareness.
- Given the well-established presence of the Ferinject product in the Australian market and its extensive use, the Committee considered that the reported side effect is unlikely to pose a significant safety concern to the majority of patients. Without a balanced representation of the actual risk, the emphasis placed on this condition appears inflated and disproportionate to its clinical significance, particularly in light of the product's long-standing history and widespread use.
- Whilst the material may have promoted awareness of the mechanism and potential for secondary complications of prolonged hypophosphatemia (hypophosphataemic osteomalacia) for at-risk patients, the overall effect blurred the distinction between transient and severe prolonged hypophosphatemia, creating an impression that the more commonly observed mild form of hypophosphatemia carried similar risk of severe sequalae. The Committee considered the material was misleading.
- The Committee reminded companies of the importance of maintaining consistency with the PI. While the subject company expressed their view that the term 'mostly transient' does not reflect what they consider to be the emerging and most accurate body of evidence, the Committee emphasised that such interpretations should not generally override the information in the PI and were not a valid reason to refrain from using the term in the material.
- With regards to the subject company's view of what they consider to be emerging and the most accurate body of evidence, the Committee noted that claims deriving from interpretations of evidence that differ from that presented in a comparator's approved PI would be expected to be supported by a very high level of scientific justification and vigilance in providing a balanced presentation of the material. The Committee noted this was not evident in the materials and considers the subject company's interpretation not a valid reason to refrain from using the term in the material.
- The Committee concluded that the material's emphasis on and repetition of the incidence of hypophosphataemia was inconsistent with the Ferinject PI.

Decisions and Sanctions

In conclusion, the Committee made the following decisions:

- By unanimous decision, the materials breached Overarching Principle 3, because the information was not balanced adequately to support the product's appropriate use.
- By unanimous decision, the materials breached Overarching Principle 7, because information relevant to prescribing, in particular product and safety information were not clearly communicated in all promotional materials and did not support proper assessment of their risks and benefits.
- By unanimous decision, the materials breached Overarching Principle 8, because the materials were inconsistent with the Australian Product Information (including claims about competitor products), irrespective of the source on which the claim is based.
- By unanimous decision, the materials breached Overarching Principle 1. The Committee acknowledged that because the materials exaggerated and were misleading, the materials could not support the quality use of medicines.
- By unanimous decision, the materials breached Section 1, because the information, claims and graphical representations were not balanced adequately and misled. The cited references did not provide the appropriate level of evidence for the claim being made, nor allowed HCPs to independently evaluate the validity of results.
- The Committee did not adjudicate the allegation of Section 1.1, because it was not raised in ICD.
- The Committee did not make any findings as to whether the poster breached the Code due to reasons outlined on page 4.

Committee's consideration of the sanctions:

- The Committee determined the materials had minimal safety implications to patient wellbeing.
- The materials were likely to have affected how the medical profession will prescribe the product, however, the Committee did not believe this would be a 'major effect'.
- Due to these reasons, the Committee was satisfied the breaches arising from the materials should be categorised as moderate.
- The Committee considered what sanctions were appropriate, having regard to the following factors:

    a. Whether the breach should have been clearly evident to the subject company;
    b. Length of time that the materials have been in use;
    c. The number and type of alleged breach/es;
    d. Circumstances in which the activity took place – and whether any explanation was offered by the subject company;
    e. Whether a subject company engaged in ICD in good faith;
    f. Whether a subject company made reasonable concessions in response to ICD or the complaint itself; and
    g. Where prescribing behaviour may be affected, the likely degree of the effect.

Decisions and Sanctions continued

Sanctions:

- The Committee determined that a fine was appropriate, and this be at the maximum fine threshold associated with a moderate breach.
- The Committee considered the breaches should have been clearly evident to the subject company. The company should have recognised the materials as comparative and extra care should have been taken to ensure that any comparison does not mislead by distortion, by undue emphasis or in any other way.
- The Committee imposed the following sanctions:

    a. Single monetary fine of $150,000.
    b. Withdrawal of materials found in breach (where they are still in circulation)

- The Committee did not impose corrective action, determining that a monetary fine coupled with the withdrawal and cessation sanction would be adequate.

- end -