Prescription Medicines Code of Practice Authority

Case report

Case number	Case/0395/12/24
Complaints received	12 and 18 December 2024
Case title	Allegations regarding information contained on the Vifor Vault website
Complainant	Named, contactable complainant – role not specified
Respondent	CSL Vifor
Applicable ABPI Code	2024
Clauses raised	5.1, 6.5, 8.5, 16.1 and 26.1
Panel decision	27 November 2025
Respondent undertaking	08 December 2025
Appeal Board review	17 December 2025 [All completed cases are reviewed by the Appeal Board – see Paragraph 15.4 of the Constitution and Procedure]

Case summary

This complaint related to materials on CSL Vifor's "Vifor Vault" – a website designed for health professionals, which housed materials related to CSL Vifor's medicines and therapy areas.

The Panel considered this complaint to allege:

- CSL Vifor's medicine, Ferinject (ferric carboxymaltose), was promoted to the public by a patient leaflet being accessible by a Google search for "*vifor vault*".
- The Vifor Vault included a recording of a presentation that was "*approved over 2 years ago in 2022*".
- The recording used the term "*new*" to describe Kapruvia (difelikefalin acetate), when that product had been licensed and available for two years.

The outcome under the 2024 Code was:

Breach of Clause 6.5	The word "new" must not be used for products that have been generally available for more than 12 months
Breach of Clause 16.1	Promotional material about prescription only medicines directed to a UK audience must comply with all relevant requirements of the Code
Breach of Clause 26.1	Promoting a prescription only medicine to the public

No Breach of Clause 5.1(x2)	Requirement to maintain high standards

No Breach of Clause 8.5	Requirement that materials which are still in use must be recertified at intervals of no more than two years

This summary should not be relied upon in isolation.
For full details, please see the full case report.

Full case report

Case preparation

1. The PMCPA received a complaint about CSL Vifor from a contactable complainant.

2. The complaint is at **Annex A**.

3. This complaint related to materials on CSL Vifor's "Vifor Vault" – a website designed for health professionals, which housed materials related to CSL Vifor's medicines and therapy areas.

4. The Panel considered this complaint to allege:

   a. CSL Vifor's medicine, Ferinject (ferric carboxymaltose), was promoted to the public by a patient leaflet being accessible by a Google search for "*vifor vault*".

   b. The Vifor Vault included a recording of a presentation that was "*approved over 2 years ago in 2022*".

   c. The recording used the term "*new*" to describe Kapruvia (difelikefalin acetate), when that product had been licensed and available for two years.

5. The PMCPA case preparation manager asked CSL Vifor to provide a complete response to the complaint and consider the requirements of Clauses 5.1, 6.5, 8.5, 16.1 and 26.1 of the 2024 Code.

6. The response from CSL Vifor is at **Annex B**. CSL Vifor conceded that it was "*at risk of breaching Clauses 16.1 and 26.1*" in relation to allegation 1. However, it did not accept expressly any of the allegations or acknowledge any breaches.

7. The case preparation manager referred the case to the Code of Practice Panel to consider and provide its ruling. The Panel considered the information provided by both parties in full.

Panel ruling

Allegation 1 – promotion of Ferinject to the public

8. The complainant alleged that they had searched for "*vifor vault*" on Google and been able to access a leaflet on the Vifor Vault website that amounted to promotion of Ferinject to the public.

9. CSL Vifor submitted that the Vifor Vault website:

   a. was intended for health professionals as a repository for materials related to its medicines and therapy areas

   b. was not intended to be accessible via search engines

   c. had a pop-up screen before granting access to the site, on which users were asked to self-certify if they are a health professional or a healthcare decision maker (users who clicked 'no' were redirected to CSL Vifor UK's corporate website).

10. However, CSL Vifor acknowledged in its response:

   a. two documents (pdf files of the Ferinject patient leaflet referred to by the complainant and a 'Kapruvia Algorithm') could be viewed *without* needing to self-certify as a health professional when the search terms "*vifor vault*" or "*vifor vault uk*" were used within Google

   b. both documents were intended for health professionals and should not have been visible to members of the public

   c. both documents were "*at risk of breaching Clauses 16.1 and 26.1*" but "*very specific search terms were required to access these documents, and entry via the vifor vault itself would result in the required disclosures (HCP or not) prior to access to these and all other content.*"

11. Although CSL Vifor's submission referred to two documents (the Ferinject patient leaflet and the Kapruvia Algorithm), the Panel limited its ruling to the Ferinject patient leaflet because that was the subject of the complaint.

Clause 26.1 – prescription only medicines must not be advertised to the public

12. The Panel relied upon the following points:

   a. Clause 26.1 prohibited the advertising of prescription only medicines to the public.

b. Companies can provide non-promotional information to patients about a medicine they have been prescribed, provided that such information complies with the Code (see the supplementary information to Clause 26.2 'Information to the Public').

c. It is an established principle that material about a medicine directed at patients who have been prescribed it should not also be accessible to the public unless it is suitable for that audience.

d. The supplementary information to Clause 16.1 'Website Access' stated:

"*Unless access to promotional material about prescription only medicines is limited to health professionals and other relevant decision makers, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified.*"

13. The Panel concluded that, in the specific context of this case, Ferinject had been promoted to the public because the Ferinject patient leaflet:

a. was openly accessible to members of the public, and

b. included the brand logo, medicine name and indication.

14. The Panel acknowledged that the complainant had used a specific search term but considered that it was nevertheless important that material intended for health professionals included a requirement to self-certify as one. CSL Vifor accepted that the complainant in this case had not been required to self-certify as a health professional.

15. Given its conclusion that Ferinject had been promoted to the public, the Panel ruled a **breach of Clause 26.1**.

Clause 16.1 – promotional material about prescription only medicines must comply with the Code

16. Clause 16.1 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.*"

17. The supplementary information to Clause 16.1 referred to the requirement to ensure information for the public and promotion to health professionals are clearly separated.

18. Given its ruling of a breach of Clause 26.1 above, and that the requirement to self-certify as a health professional was not in place for the Ferinject patient leaflet, the Panel ruled a **breach of Clause 16.1**.

Clause 5.1 – requirement to maintain high standards

19. In relation to the Clause 5.1 requirement to maintain high standards, CSL Vifor submitted that:

a. this was a technical issue related to how two pdf files were made non-indexable via search engines,

b. this technical issue did not apply to any other content on the Vifor Vault,

c. its intention was for this content to only be visible to the intended audience.

20. The Panel accepted these submissions from CSL Vifor. The Panel also took account of the very specific search term used by the complainant and that the complaint was limited to the patient leaflet.

21. The Panel concluded that CSL Vifor had not failed to maintain high standards and that the breaches of Clauses 26.1 and 16.1 were sufficient in relation to this matter. The Panel ruled **no breach of Clause 5.1**.

Allegation 2 – Kapruvia presentation recording approved more than two years ago (Clause 8.5)

22. In relation to the presentation recording, the complainant alleged that the date of approval was "*old*" (2022).

23. The Panel interpreted the complainant's allegation to be that:

a. the presentation recording was certified in November 2022 (the date visible in the screenshot provided by the complainant),

b. this was more than two years before the date of the complaint (December 2024), and

c. this was a breach of the Clause 8.5 requirement for materials that are still in use to be recertified at internals of no more than two years.

24. CSL Vifor submitted that the presentation took place in November 2022, the recording of it was certified in January 2023 and then recertified in March 2023. However, CSL Vifor provided the Panel with a copy of the certificate showing that the recording had actually been recertified on 16 May 2023.

25. The Panel was therefore satisfied that, at the time of the complaint, the recording had been certified within the last two years. The Panel ruled **no breach of Clause 8.5**.

Allegation 3 – Kapruvia presentation recording refers to Kapruvia as "new"

26. The complainant alleged that the presentation recording referred to Kapruvia (difelikefalin acetate) as "*new*" despite it having been licensed and available for two years.

Clause 6.5 – use of the word "new"

27. Clause 6.5 of the Code stated:

"*The word 'new' must not be used to describe any product or presentation which has been generally available, or any therapeutic indication which has been promoted, for more than twelve months in the UK.*"

28. CSL Vifor submitted that:

a. Kapruvia received its marketing authorisation on 29 April 2022.

b. The word "*new*" was used in the context of *"New therapies for CKD-aP*" on the outline slide. That slide was shown multiple times, including prior to a discussion of Kapruvia.

c. At the date the meeting was held (November 2022), Kapruvia had been licensed for less than 12 months.

d. At the date of the screenshots that formed this complaint (18 December 2024), Kapruvia had been marketed for more than 12 months.

e. The material at issue was valid because it had been reapproved for two years on 16 March 2023.

f. Viewers of the presentation recording would recognise the date on which the meeting was held and review the video within this context i.e. that Kapruvia was 'new' at the time of the recording.

29. The complainant provided screenshots of some of the presentation slides. CSL Vifor provided the Panel with a copy of the full presentation slides, but not the video itself. Therefore the Panel did not know what commentary (if any) had been made by the speaker about the "*new therapies*". However, the Panel considered that it could base its ruling on the content of the slides, including the screenshots that formed part of the complaint.

30. The Panel did not have a copy of the webpage on which the presentation recording was hosted. The Panel was therefore unaware of how the presentation recording was described or what information a viewer would have been provided with before accessing the material.

31. The Panel took account of the following points:

a. Kapruvia received its marketing authorisation on **29 April 2022**.

b. The date of reapproval given by CSL Vifor in its letter of response (16 March 2023) was incorrect – the presentation recording was reapproved on **16 May 2023**.

c. The presentation recording was available on the Vifor Vault website at the time of the complaint (**December 2024**).

32. The complainant's screenshot showed that the presentation included the date "*November 2022*" in very small font in the footer of the first slide. However, based on the material provided to it, the Panel considered that it was not immediately clear to a viewer of the video that it was a recording of a meeting that had taken place in November 2022.

33. The Panel was concerned that material that used the word "*new*" had been recertified in May 2023, more than 12 months after Kapruvia received its marketing authorisation.

34. The Panel concluded that the word "*new*" had been used to describe a medicine that had been generally available for more than 12 months in the UK. The Panel therefore ruled a **breach of Clause 6.5**.

Clause 5.1 – requirement to maintain high standards

35. Although the Panel was concerned that the material had been recertified containing the word "*new*", the Panel did not consider that there were any additional allegations or factors to suggest that CSL Vifor had failed to maintain high standards in this case. The Panel therefore ruled **no breach of Clause 5.1**.

Annex notes

The Panel used square brackets in Annex A and Annex B to anonymise and redact information in the complaint and response. This is for the purposes of:

- protecting the confidentiality of named individuals,
- protecting company information that is commercially sensitive or confidential,
- anonymising third parties that have not had a chance to comment on the case, and/or
- ensuring that material that may be a breach of the Code is not made publicly available when the case report is published.

For similar reasons, any attachments provided to the PMCPA with the complaint and response are not included in this case report.

The wording of the complaint (Annex A) and the company response (Annex B) is otherwise copied in full below.

Annex A – The complaint

“Dear SIR

Please see Ferinject material open to the public which would be promotion to the public. It comes up on search from google when typing vifor vault

tHE GOOGLE SEARCH IS MISLEADING AS IT SAYS

CSLVifor – Vifor Vault [Vifor Vault URL and file pathway]

PDF

This leaflet explains what Ferinject is, how it is used and what you can expect from your treatment. If you have any additional questions or concerns, ...

[Link to pdf of Ferinject patient leaflet]

Regards”

“Dear Sir

Additionally I was looking and I came across this

[Link to webinar]

Please see webinar.

[Image showing the title: [Named health professional]: Are we just scratching the surface of CKD-associated pruritus?]

it looks like the date it has been approved is old ie 2022

And it uses word NEW when Kapruvia has been licenced for I think 2 years

Attached are screenshots

Regards”

Further information provided by the complainant

The case preparation manager requested further information from the complainant. The complainant’s response is copied in full below (with redactions as described in the Annex notes section above).

“I am not tech savvy. This is all very complicated.

1ST complaint

This is what I wrote in google

[screenshot provided showing a Google search for “vifor vault”]

You can access it yourself, It is the second link on the page

There is no pop up box

Second complaint

After I saw this, I went to explore Vifor's websites and the vault.

I saw Kapruvia on the webinar and it being referred to as NEW

I don't know the exact pharmacy laws but I would think it needs to be approved so it is relevant, This was approved over 2 years ago in 2022, and is using the word NEW and I have read Kapruvia is not new. It has been licenced and available for 2 years. It is still up on website for people to see and it they are saying this drug is new and people can see it 2 years on, then that is not accurate

Regards"

Annex B – CSL Vifor's response

"Thank you for your letter dated 10 January 2025 in which you raise two complaints from an individual who has not described themselves or responded to a request to disclose any interest in the matter of complaint or in CSL.

We note that this is one of a number of complaints communicated to CSL Vifor UK from one or more individuals in a short period of time, and while we are committed to engage in self-regulation and in the complaints process with transparency and professionalism, we would like to highlight that the burden of proof for any complaint resides with the complainant and we hope that only cases where such proof has been provided are raised with us to respond to.

Furthermore, we fully support the need to accept concerns from individuals who provide limited information where this aligns with the objectives of the Code and the principles of the ABPI. However, we also recognise that complaints can be raised for other, negative, reasons and we rely on the robust application of the constitution and procedure of the Code to ensure all cases are dealt with fairly. We are particularly concerned that the individual has not fully described themselves to you or provided clarity regarding interest with CSL Vifor.

The 2 complaints raised are:

1. Public access to Ferinject material hosted on CSL Vifor UK vault, based on a google search of the term 'vifor vault'
2. Availability of the Nephrology Summit and alleged use of the work 'new' in relation to Kapruvia as part of a presentation given by an expert nephrologist.

In your letter you have asked us to consider the requirements of Clauses 6.5, 8.5, 16.1, 26.1 and 5.1 of the 2024 Code.

Taking each complaint in turn:

1. Vifor Vault

The Vifor Vault is a repository for materials related to CSL Vifor medicines and therapy areas. The site, which consists of a wireframe combined with content (enclosures 1), is intended for HCPs, who are directed to the requested or relevant content by either CSL Vifor's customer relationship management system or through HCP adverts. The wire frame and content were appropriately reviewed and certified. The site is not intended to be accessible via Google (or other) search engines and we note that the site itself was not visible on the Google search result provided with the complaint or our subsequent searches. When the site was initially set up, checks were made to ensure the site and / or content were not visible via Google search, and we understand that in January 2023 we had to specifically raise the need to have the site made invisible to search engines, to ensure this was in place.

When accessing the site itself [URL provided], the audience is shown a screen that requests the user to identify whether they are a UK HCP or healthcare decision maker, or neither of these things (enclosure 1 and 2). We believe that due to being accessible only via an invite / link and the pop-up requesting identification as an HCP or healthcare decision maker prior to entry to the site, the content was visible to only the appropriate audience. If the user declared that they were not an HCP or healthcare decision maker, they were redirected to the CSL Vifor UK corporate website [URL provided]. Please note that the Vifor UK Corporate site does not expose or direct the user to any product related content, including publicly available content such as the SPC, as the user is not thought to be searching for any product content.

We acknowledge that when the specific search term ‘vifor vault’ is entered into Google, it does return a search that includes the Ferinject patient leaflet pdf (enclosure 3) labelled as ‘Downloaded by PMCPA - 5-Ferinject from 2nd link in complaint’ in the attachments included with the letter of complaint dated 10 January 2025. We note that the search result as provided in the letter of complaint is not the same as when we searched for this term but acknowledge that the Ferinject pdf was visible when we searched for ‘vifor vault uk’.

We acknowledge that while the Vifor Vault web site was not visible, this document (Ferinject patient leaflet pdf), and also the Kapruvia Algorithm pdf (enclosure 3) were visible to the public when the search terms ‘vifor vault’ or ‘vifor vault uk’ were used within Google, without a pop-up requesting identification as an HCP or otherwise. Both documents are intended for HCPs and should not be visible to members of the public, although we note that very specific search terms were required to access these documents, and entry via the vifor vault itself would result in the required disclosures (HCP or not) prior to access to these and all other content.

Based on your letter and our investigation, on Thurs 16 January 2025 we requested our digital agency to remove the 2 flagged PDFs from view and this was done on the same day. At the same time, we requested a check that the entire site not be visible when searching for Vifor vault or vifor vault uk, which was confirmed on Monday 20 Jan 2025. To be additionally sure that no content was visible, even with a very detailed google search, and due to up-coming SPC changes, we requested that the entire vault site be placed ‘under construction’ and not visible to any user on Friday 24 January 2025.

The fault appears to be linked to how these specific pdf items were made non-indexable via search engines, which with our prior digital agency was a manual process for each individual item. With a recent system update, the manual ‘fix’ was deleted, making the 2 items visible. This issue did not apply to other content or the site in general.

As we update our website and content, we will ensure that all appropriate requirements of the ABPI Code are reflected in its content and access to it.

Based on your letter and our findings, we can see that two items intended for HCPs were visible to members of the public and are, therefore, at risk of breaching Clauses 16.1 and 26.1, but this would only be possible through use of very specific search wording.

Based on the technical nature of the issue and the intent to make our content visible to only the intended audience we do not feel that we have breached Clause 5.1 of the ABPI Code.

2. The Nephrology Summit

The CSL Vifor Nephrology Summit was a hybrid promotional meeting held on Friday 25 November 2022 at The Midland Hotel, Manchester and online. The meeting was appropriately reviewed and approved, including the slides for the session created by [named speaker]: Updates on management of CKD-associated pruritus, which is the subject of the complaint (at the meeting titled ‘Are we just scratching the surface of CKD-aP’).

This session, together with the rest of the meeting was made available on CSL Vifor’s vault website after appropriate review and approval for online use. The recording in question was approved and reapproved on 12 January 2023 and 16 March 2023, respectively (enclosure 6). All content was approved with expiry or reapproval required after 2 years.

The presentation in question includes an overview of the management of CKD-associated pruritis (CKD-aP) and included mention of the CSL Vifor Medicine Kapruvia (difelikefalin

acetate), which received its marketing authorization on 29 April 2022 and was approved by NICE in May 2023.

The use of the word ‘new’ was as part of the bullet ‘new therapies for CKD-aP’ on the outline slide at the start of [named speaker’s] presentation and prior to each section of [their] talk, including prior to talking about difelikefalin. When the meeting was held, Kapruvia had been licensed for less than 12 months. We recognise that when the content was reviewed by the complainant (and when screenshots were taken on 18 Dec 2024), prior to the letter of complaint, Kapruvia had been marketed for more than 12 months, but the materials in question were valid in that they had been approved for 2 years on 16 March 2023. We would expect the audience of this and other content from the Nephrology Summit to recognise the date on which the meeting was held and review the video within this context, including the linking of difelikefalin with being a ‘new therapy for CKD-aP’ at the time of the meeting.

We feel that the content of the meeting, including [named speaker’s] presentation, was and continues to be of value to HCPs working with patients with chronic kidney disease and the content does not mislead in terms of patient management or medicine benefits and risk. The content of the meeting was due for withdrawal early in 2025, but has already been withdrawn, and we will ensure that the requirements of Clause 6.5 are reflected in the updated content and the meeting remains current and relevant in all ways expected by the ABPI Code.

Based on the date of the Nephrology Summit meeting and the date of the approval and availability of the recording, we do not believe we have breached Clauses 6.5 or 8.5 of the ABPI Code and have, at all times, maintained high standards.

In summary, we can confirm that due to inadvertent loss of file tagging, two medicine related PDF documents intended for an HCP audience were visible to members of the public, who searched for Vifor Vault, without an alert that the content was for an HCP audience only. These and other content have been removed from view while corrections are put into place. We can also confirm that recorded presentations from the Vifor organized Nephrology Summit, including one by [named speaker], held on the 25 November 2022, were available within the Vifor vault from March 2023. Within this presentation, dated 25 November 2022, difelikefalin is discussed after being introduced as a new therapy for CKD-aP and these materials were approved for 2 years on 16 March 2023.”