CASE/0435/01/25 *NO BREACH OF THE CODE*

COMPLAINANT v CSL VIFOR

Allegations regarding the arrangements of a symposium

CASE SUMMARY

This case was in relation to a symposium at a conference held in Italy in 2023. The complainant alleged that the slides had not been certified and that, although it was a promotional meeting, there was no prescribing information or black triangle and it was "not transparent to UK delegates it was promotional".

The outcome under the 2021 Code was:

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**
No Breach of Clause 5.1 (x2)	**Requirement to maintain high standards at all times**
No Breach of Clause 8.1	**Requirement to certify promotional material**
No Breach of Clause 8.2	**Requirement that events/meetings involving travel outside the UK, unless the company's only involvement is to support a speaker to present at the meeting, must be certified**
No Breach of Clause 12.1	**Requirement to include prescribing information**
No Breach of Clause 12.2	**Requirement that the prescribing information includes the specified information**
No Breach of Clause 15.6	**Requirement that promotional materials and activities must not be disguised**

This summary is not intended to be read in isolation.
For full details, please see the full case report below.

FULL CASE REPORT

A complaint about CSL Vifor was received from an anonymous, non-contactable complainant who described themselves as a healthcare professional.

COMPLAINT

The complaint wording is reproduced below:

> "'Targeting the needs of ANCA Vasculitis Outcomes Vifor Symposium'. UK HCPs were sponsored/supported to go to EULAR in 2023. (EULAR conference)

No certification of slides. According to PMCPA as UK HCPs/delegates for overseas symposium, needs AQP signatory certification.

It was Promotional meeting

But No Prescribing information
No black triangle
Not transparent to UK delegates it was Promotional
Not certified

Vifor Breached ABPI Code"

When writing to CSL Vifor, the PMCPA asked it to consider the requirements of Clauses 8.1, 8.2, 12.1, 12.2, 12.7, 15.6, 5.1 and 2 of the 2021 Code.

CSL VIFOR'S RESPONSE

The response from CSL Vifor is reproduced below:

"Thank you for your letter dated 4th February 2025, in which you raised an allegation from an anonymous HCP.

We note that this is one of a series of allegations/complaints communicated to CSL Vifor from an anonymous individual in a short period of time. Whilst we remain committed to self-regulation and to addressing complaints received with transparency and professionalism, we would like to emphasize that the burden of proof resides with the complainant. We trust that only the cases in which the PMCPA deem the complainant to have provided sufficient evidence are raised with us for consideration.

We fully support the principles of accepting concerns from anonymous complainants where this aligns with the objective of the Code and the principles set forth by the ABPI. However, it is also important to recognise and highlight that complaints can be raise [sic] with other, less constructive intentions.

We have reviewed the requirements of Clauses 8.1, 8.2, 12.1, 12.2, 12.7, 15.6, 5.1 and 2 of the 2021 Code in relation to this allegation.

Our response will focus and address the 2 separate aspects of the event and CSL Vifor activities:

1. CSL Vifor Global contracted with two UK HCPs to speak at CSL Vifor Globally organised symposia (2 separate events) at EULAR 2023 which was held in Milan, Italy.
   [Named UK HCP 1] and [named UK HCP 2] were contracted as per Enclosure 1 and 2 respectively. [Named UK HCP 1's] contract also included support to attend the congress, including hotel and congress registration, and the engagement was reviewed and approved by the then Head of Medical Compliance ([named]).
   [Named UK HCP 2's] contract was only for the speaker engagement, and the support for attendance to EULAR was managed separately via item 2 below.

The UK's only role with the symposia was to help facilitate the global team's engagement with the UK HCPs, and the UK company did not have any role in the design or delivery of the company stand or symposia or in the invitation of HCPs, including UK HCPs, to any of the globally organised items.
Based on this lack of involvement with the stand and symposia, we do not believe the UK company had any responsibility to review and approve the symposia or company stand.

Notwithstanding our rationale above, the presentations were certified by a UK Final Medical Signatory ([named]). We are unable to clarify why this decision was undertaken as all involved people have since left the company. Given that CSL Vifor were under PMCPA audit at the time we suspect an extremely cautious approach may have been applied. The symposia were developed and approved by the Global team according to the local (Italy) and EFPIA requirements.

Our global colleagues produced an email advert (e-blast) for the symposia via the EMJ. The email e-blast states 'not intended for Healthcare Professionals from the UK', this e-blast was certified by a UK Medical Signatory again, the decision and rationale to certify is not recorded.

A briefing for all UK CSL employees in attendance clearly documents that no UK HCPs were to be invited to the CSL Vifor Global symposiums.

In summary, we can confirm that 2 UK HCPs were engaged by the above country CSL Vifor team to deliver presentations at separate symposia during the EULAR congress in Italy. Both engagements were managed and reviewed appropriately and, where required, approved by UK Signatories. As the UK CSL Vifor team had no role in the design, delivery or attendance to the company stand or symposia, we do not believe UK review and approval were required for any of the events described.

2. In relation to the provision of support to UK HCPs, 8 UK HCPs were supported to attend the 2023 EULAR congress in Italy by CSL Vifor UK:
[list of eight names, including UK HCP 2].

   The list of UK HCPs and proposed arrangements were reviewed and approved by a UK Final Signatory ([named]), as required by the UK Code.

   CSL Vifor UK staff were briefed not to invite any of the supported HCPs, or other UK HCPs to either the stand or symposia organized by the global team.

In summary, CSL Vifor UK supported a number of UK HCPs to attend the 2023 EULAR congress in Italy and all arrangements were appropriately reviewed and approved as required by the ABPI Code.

In summary, CSL Vifor UK supported HCPs to attend EULAR 2023 in Italy and the above country CSL Vifor teams also arranged the company stand and 2 symposia, which included UK speakers. However, UK HCPs were not invited to attend the stand or symposia by UK staff.

CSL Vifor therefore do not accept any breaches of Clauses 8.1, 8.2, 12.1, 12.2, 12.7, 15.6, 5.1 and 2 of the 2021 Code.

We trust that this response addresses the allegations raised in your letter. We remain committed to upholding the highest standards of compliance and transparency."

PANEL RULING

The complaint was about a symposium at a conference held in Italy in 2023. The complainant alleged the following:

- the slides had not been certified
- it was a promotional meeting, but there was no prescribing information or black triangle
- it was "not transparent to UK delegates it was promotional".

CSL Vifor submitted that two UK health professionals were contracted by CSL Vifor Global to deliver presentations at separate symposia during the conference. The Panel interpreted the wording of the complaint to relate to only one symposium. Having compared the title of the symposium provided by the complainant with the information in an "e-blast" provided by CSL Vifor, the Panel determined that the symposium at issue was titled "Targeting unmet needs in ANCA-associated vasculitis—can we do better?" and involved a Chair and three other speakers, including one of the UK health professionals identified in CSL Vifor's response ([named UK HCP 1]).

UK companies have responsibilities under the Code for events/meetings which they organise and when UK delegates are supported and/or UK speakers are contracted to go to events/meetings outside the UK.

The supplementary information to Clause 8.2 'Presentations by UK Speakers at Events/Meetings Held Outside the UK' stated:

"When a pharmaceutical company based outside the UK arranges via a UK company for a UK speaker to present at an event/meeting to be held outside the UK, then that speaker's presentation materials do not need to be certified or examined by the UK, provided there are no UK delegates and the UK company has no role whatsoever in relation to the event/meeting or the presentation. In such circumstances, the event/meeting arrangements, in as much as they apply to the UK speaker, will not have to be certified or examined."

The Panel noted CSL Vifor's submission that "The UK's only role with the symposia was to help facilitate the global team's engagement with the UK HCPs, and the UK company did not have any role in the design or delivery or the company stand or symposia or in the invitation of HCPs, including UK HCPs, to any of the globally organised items."

The Panel took particular note of the following information from CSL Vifor's response:

- The symposium at issue was developed and approved by CSL Vifor Global (a non-UK company) according to the local (Italy) and EFPIA requirements.

- The speakers at the symposium, including the UK health professional, were contracted by CSL Vifor Global.

- The e-blast promoting the symposium stated: “Not intended for healthcare professionals from UK.”

- The briefing document for UK staff attending the conference stated:
  - *“No UK-based CSL Vifor staff (regardless of whether their role is local or global) may be present on either the CSL Vifor commercial or medical stands”*
  - *“**What we can’t do:***
    - Invite any UK HCP to, or promote attendance at, any CSL Vifor-sponsored global events
    - Use printed or digital materials with HCPs in Milan
    - Be present in any capacity on the CSL Vifor booth where global materials and advertising are present – this includes arranging to meet UK HCPs at the booth
    - Encourage UK HCPs to go to the booth”.

The Panel considered that the symposium was not intended for UK health professionals and there was no evidence that UK health professionals had attended the symposium. CSL Vifor UK supported eight UK health professionals to attend the wider conference, but staff were briefed not to invite these health professionals (or other UK health professionals) to either the stand or the symposia organised by the global team. The e-blast included a clear statement that it was not intended for UK health professionals.

In the Panel’s view, the fact that a UK signatory had approved the e-blast and the UK health professional’s presentation did not amount to the UK company having had a role in the symposium. The Panel took account of the wording of the certificates, which did not include any reference to the ABPI Code or use for a UK audience, and considered that the company had likely been acting with an abundance of caution.

The Panel concluded that the UK company did not have responsibility for the content of the symposium at issue.

Clause 8.2 required that all events/meetings involving travel outside the UK, unless the company’s only involvement is to support a speaker to present at the meeting, must be certified in advance as set out in Clause 8.1 or by an appropriately qualified person signatory (AQP signatory). The Panel noted the Appeal Board’s determination in Case AUTH/3825/9/23 that Clause 8.2 did not extend to certification of speakers’ materials and that such materials may fall to be certified under Clause 8.1 or Clause 8.3 in certain situations. The Panel determined that the complainant’s allegation was limited to certification of the slides for the symposium and that there was no allegation regarding certification of the event arrangements. The Panel therefore ruled **no breach of Clause 8.2**.

Clause 8.1 dealt with the requirements for certification of promotional materials by a medical signatory. The Panel concluded that there was no requirement for the slides presented by the four speakers at the symposium to be certified in line with the ABPI Code and ruled **no breach of Clause 8.1**.

The complainant alleged that it was “not transparent to UK delegates” that the symposium was promotional. The Panel considered that there was no evidence that UK delegates had been invited to or attended the symposium. The Panel noted that the complainant bore the burden of proof and did not consider that they had provided evidence to support their allegation. The Panel therefore ruled **no breach of Clause 15.6**.

The complainant alleged that there was no prescribing information. Having determined that the complainant had not established that the UK company was responsible for the content of the symposium, the Panel ruled **no breach of Clause 12.1 and Clause 12.2**.

The complainant also alleged that there was no black triangle. The Panel noted that, in error, the case preparation manager had asked CSL Vifor to respond to Clause 12.7 which related to prescribing information requirements for printed journals. On the basis that Clause 12.7 was not relevant to the circumstances in this case the Panel made no ruling on this clause. It decided to consider the allegation in relation to the black triangle requirements under Clause 5.1. The Panel noted its comments above that the complainant had not established that the UK company was responsible for the content of the presentation and therefore it followed that this also applied in relation to the black triangle requirements. The Panel ruled **no breach of Clause 5.1** in this regard.

Taking into account its rulings of no breaches of the Code, above, the Panel considered that the complainant had not established that CSL Vifor had failed to maintain high standards or had brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel therefore ruled **no breach of Clause 5.1** and **no breach of Clause 2**.

Complaint received **14 January 2025**

Case completed **20 November 2025**