

COMPLAINANT v CSL VIFOR

Allegations regarding a lack of certification

CASE SUMMARY

This case was in relation to two payments CSL Vifor had made to a patient organisation. The allegation was that the agreements relating to these payments had not been certified or signed before the activity to which they related had commenced.

The outcome under the 2021 Code was:

Breach of Clause 8.3	Failing to certify the written agreement for donations and grants in advance
Breach of Clause 23.2	Failing to certify the written agreement for donations and grants in advance
Breach of Clause 27.2	Failing to have a written agreement in place for donations, grants or sponsorship to a patient organisation

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	Requirement that companies must maintain high standards at all times
No Breach of Clause 8.3	Requirement to certify the written agreement for donations and grants in advance
No Breach of Clause 10.3	Requirement to have a written agreement for the sponsorship of patient organisations

**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 a contactable complainant.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected, and with the payments that were not the subject of this complaint redacted:

"I note failure of CSL Vifor to **certify** multiple agreement for [named patient organisation] in 2021/ 2022 PRIOR TO sending to patient group and prior to the activity starting.

2022

Beneficiary: [named patient organisation]

Nature of support: Support for campaign to build awareness of insights generated through quality of life survey and white paper

Amount of financial support or value/ invoiced costs: GBP25,000

Beneficiary: [named patient organisation]

Nature of support: Patient speaker attendance at CSL Vifor organised meeting to present on heart failure

Amount of financial support or value/ invoiced costs: GBP360

ABPI code clause 23.2 (current)- grants must be certified

ABPI code 27.2 and 8.3 (current) agreements with patient organisations must be certified

CSL Vifor has failed with these 2 clauses"

Further information from the complainant

"PMCPA

My second email did not send

On [link provided]

There is a link to

a. HCO Support Request Form UK

There is a link to

b. Section 172 Statement

These are available to public and should be certified but have not been certified. There is no job bag number.

Even if argued that the HCO request form is for HCO, this should at-least have been examined. It has not been examined. Breach.

Disclosure on CSL website [link provided]

CSL Vifor Patient Organisations - Methodological Note

[same list of payments as in the original complaint above]

This in scope of ABPI code as it discusses United Kingdom and is available to the public. It must be certified or examined

It has not been certified or examined. breach

Under [link provided] I note that PV email address is not current PV email address and address is not current CSL Vifor address ie

CSL Vifor has relocated from

Vifor's representative in the UK for data privacy purposes: Vifor Pharma UK Ltd. Second Floor, Waterfront Watermans Business Park Kingsbury Crescent Staines-upon-Thames TW18 3BA United Kingdom

Breach and potential impact patient safety"

When writing to CSL Vifor, the PMCPA asked it to consider the requirements of Clauses 8.3, 10.3, 23.2, 27.2, 5.1 and 2 of the 2021 Code.

In accordance with the PMCPA Constitution and Procedure, the case preparation manager advised CSL Vifor that it was not required to respond to allegations in relation to the Section 172 Companies Act Statement, the Methodological Note on the EFPIA disclosure of transfer of value requirements, or the Privacy Notice for Medical Information queries. The case preparation manager also advised CSL Vifor that the complaint related solely to agreements with the named patient organisation and therefore it was not required to respond with regard to any other third-party beneficiaries.

CSL VIFOR'S RESPONSE

The response from CSL Vifor is reproduced below:

"Thank you for your letter dated 23rd January 2025, in which you raised an allegation from a contactable complainant related to:

- Certification of multiple agreements with [named patient organisation] in 2021 and 2022
- Failure to certify 'HCO Support Request form UK' and 'b. Section 172 Statement'
- Use of e mail address and office address in the context of CSL Vifor's office move

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 complainants 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.

The complainant alleges that CSL Vifor UK has failed to certify multiple agreements for [named patient organisation] in 2021/2022. We find it difficult to understand how such an allegation can be substantiated based on screenshots of the patient organisation disclosure page which is our global corporate website, and does not require certification in itself. We do not believe that the complainant has provided any evidence to support their allegation. We also note that the question of certification of the corporate disclosure site was raised in Case 0401/12/24: – Allegations about Disclosure Website, where you wrote to us on 30 January confirming that a *prima facie* case had not been established.

As you may recall, grant agreements with patient organisations including [named patient organisation], were reviewed during our September 2023 PMCPA audit, when observations were made with actions plans in response. As any relevant observations have already been addressed in the 2023 audit and given the lack of evidence provided by the complainant, we hope we can consider this matter (the subject of patient agreements from 2021/22) closed.

On a slightly different note, we are concerned that the complainant may have been privy to our PMCPA audit report as the details of such agreements are not public knowledge and are not known outside of CSL Vifor UK.

Regarding the complainant's allegations concerning the 'HCO Support Request Form' certification, we again struggle to understand how this conclusion could be reached solely based on the publicly available information. We do not believe that this form requires certification under Clause 8 of the ABPI Code. However, we have nonetheless chosen to certify it.

The complainant's further statement that 'this is in scope of the ABPI Code as it discusses UK and is available to the public' lacks clarity. It is unclear what specific aspect this comment pertains to. Therefore, we have not addressed this comment, nor do we believe the page on the corporate CSL website is in breach of the ABPI Code.

We have attempted to access the documents via the link provided by the complainant but have been unable to replicate them via the link. Consequently, we cannot assess this page against the allegations.

However, we can confirm that CSL Vifor has moved office locations, and a Royal Mail re-direction is in place from our previous address. The email address [address provided] remains a live and monitored inbox. Furthermore, our Data Protection Officer's email address [address provided], is monitored and current. As such, we believe there is no risk to patient safety and no breach of the ABPI Code, as all modes of contact remain valid and operational.

As directed by your letter, we have carefully reviewed the requirements of Clauses 2, 5.1, 8.3, 10.3, 23.2, and 27.2 of the 2021 Code considering the limited evidence provided by the complainant. Based on our review, we do not accept any breaches of Clauses 2, 5.1, 8.3, 10.3, 23.2, or 27.2."

Further information from CSL Vifor

In response to a request from the case preparation manager in relation to the payments to the named patient organisation, CSL Vifor provided the following further information:

"Thank you for your letter dated 21st March 2025, in which you raised requested information related to payments made to [named patient organisation], as identified in the complaint, during 2021 and 2022.

As requested, we have included a table of all payments to [named patient organisation] made in 2021/2022. Column 2 lists each item with each separate row numbered to correspond with the numbering applied to the letter of complaint and inclusion of wording used in Vifor's disclosure of ToV. The table provides requested dates for each item and also, where appropriate and relevant, description and explanation.

All relevant attachments are included for each payment within the enclosures. As evidenced within the table and by way of the attachments in the enclosures, all relevant engagements were appropriately reviewed and approved in advance of the activity, except those discovered in August 2023 during the collation of documentation ahead of the September 2023 PMCPA audit.

The audit report notes that an agreement for [named patient organisation] was not certified as required by the Code. CSL Vifor acknowledged in our response to the audit report that the agreement should have been certified and committed to ensuring all future agreements were compliant with the Code. We appreciate that such failures might have also occurred with prior agreements.

The deviation and CAPA mentioned within the audit report were combined and relate to two engagements with [named patient organisation]:

1. Patient Agreement for speaker at Global Townhall

In December 2022, a contract with [named patient organisation] to provide a patient advocate speaker for a global town hall was initiated. The contract was certified and signed ahead of VINCI approval (internal CRM) which contradicted our procedural document. Due to internal process deviations, the contract was delayed and therefore the speaker attended the townhall via video link without a signed contract or approval in VINCI.

2. Sponsorship agreement with [named patient organisation]

A contract was put in place with [named patient organisation] in December 2022, it was discovered in August 2023 (during discovery for the PMCPA audit) that the contract was not reviewed and certified in the UK ahead of it being sent to [named patient organisation] for signatures, this contradicted the local procedural document. The contract was managed by a global employee who failed to send the contract to the UK team for review and certification ahead of sending to [named patient organisation] for signatures.

Corrective actions taken since the September 2023 audit are detailed in the CAPA.

Retrieval of all documents from 2021/2022 has proved difficult, as was apparent in the audits done of Vifor UK by the PMCPA. Since 2022, Vifor have worked to implement the policies and processes related to engagement with patient organisations and patients and are confident that we now ensure that all such activities are managed in a way that is aligned with the requirements of the UK Code. Attached is the current procedural document that covers Relationships with Patient Organisations.

Although we acknowledge that issues raised during an audit do not preclude complaints, it appears this complaint may not have been raised with the right intentions. Furthermore, we acknowledge your statement that the complainant has declared no interest, however given that the information about the lack of certification with [named patient organisation] is not public nor disclosed publicly we struggle to see how a Complainant could have this information. This information was only accessible to certain CSL Vifor employees and ex-employees through the audit report and internal documentation relating to the deviation and CAPA. Therefore, we believe the complainant could be a current or former employee and request you press the matter further with the Complainant."

PANEL RULING

This case was in relation to allegations that agreements (related to multiple payments by CSL Vifor to patient organisations) had not been certified or signed before the activity to which they related had commenced.

On receipt of CSL Vifor's response to the complaint, and in accordance with the PMCPA Constitution and Procedure, the case preparation manager decided that a *prima facie* case had been established in relation to two payments to a named patient organisation and these were referred to the Panel for consideration. The two payments at issue were:

1. £25,000 for a sponsorship agreement with the named patient organisation to support a heart failure awareness campaign ("the sponsorship agreement"). The sponsorship agreement was dated 20 September 2022, signed on 20 October 2022 and the activity was estimated to have started between September-December 2022. CSL Vifor confirmed that it did not certify the sponsorship agreement before it was sent to the patient organisation for signing.
2. £360 for a patient organisation agreement to provide the services of a patient to speak at a meeting organised by CSL Vifor ("the patient agreement"). CSL Vifor confirmed that although the meeting was on 1 December 2022, the patient agreement

was dated 31 January 2023 and not signed until 3 February 2023 i.e. the speaker attended the meeting before a signed or certified agreement was in place.

The Panel took account of the fact that the complainant had not provided detailed evidence as part of their complaint; they had simply provided a list of agreements and alleged that they were not certified. The Panel recognised the difficulties in complainants proving the *absence* of a certificate and that it was therefore incumbent on companies to provide the necessary documentation. However, the PMCPA would not normally take forward speculative complaints where there is no basis from which it can be concluded that a company may have contravened the Code.

In this case, CSL Vifor provided the Panel with details of the sponsorship agreement and the patient agreement, from which it was clear to the Panel that the two payments in question had not been certified. In addition, the patient agreement had not been entered into in advance of the activity taking place.

CSL Vifor submitted that these matters had been considered as part of a PMCPA audit in 2023. The complainant had not referred to an audit, and neither party had provided a copy of the audit report. The Panel bore in mind that it is an established principle of PMCPA audits that materials and activities cannot be 'approved' as part of an audit and that, if a complaint is received about an activity or material that has also been reviewed as part of an audit, that complaint would be considered in the usual way. A copy of the audit report had been provided by the case preparation manager. The Panel considered that whether an audit report that had not been provided by either party to a complaint should be reviewed by the Panel would depend on the circumstances of each case. Given Vifor's detailed supplementary response, the Panel considered that it was not necessary to review the audit report as part of its consideration of this case.

The Panel noted that the sponsorship agreement and the patient agreement were with the named patient organisation.

The relevant part of Clause 8.3 of the Code required:

"The following must be certified in advance in a manner similar to that provided for by Clause 8.1: ...

- material relating to working with patient organisations as described in Clause 27 and its supplementary information*
- the written agreement for donations and grants, including where relevant internal company and service provider instructions as described in Clause 23 and its supplementary information."*

Clause 27.2 of the Code required written agreements with patient organisations in relation to donations, grants or sponsorship to be certified as set out in Clause 8.3.

Clause 10.3 of the Code required:

"Sponsorship of patient organisations (including individuals representing patient organisations to attend events/meetings) must have a written agreement in place setting out what has been agreed including, where possible, a breakdown of agreed costs."

Sponsorship agreement

Based on the complaint, and the evidence provided by CSL Vifor, the Panel concluded that the sponsorship agreement had not been certified in advance. The Panel therefore ruled **breaches of Clauses 8.3, 23.2 and 27.2**.

Patient agreement

The Panel considered that the patient agreement provided for a patient representing the patient organisation to provide a contracted service at a company organised meeting. The Panel took account of the fact that Clause 27.2 required written agreements for **donations, grants and sponsorships** (emphasis added by the Panel) to be certified in advance. In the Panel's view, there was no requirement for the agreement for contracted services with a patient organisation to be certified and the Panel therefore ruled **no breach of Clause 8.3**.

The Panel noted however that Clause 24.2 required that written agreements for contracted services must be agreed in advance of the commencement of the service. The case preparation manager had not raised Clause 24.2 with CSL Vifor and the Panel was therefore unable to make a ruling in that regard.

CSL Vifor had also been asked by the case preparation manager to respond to Clause 10.3. In relation to events, meetings and hospitality, this clause applied to sponsorship of patient organisations (including individuals representing patient organisations) and required there to be a written agreement in place, the requirements for which were set out in Clause 27.2. The Panel considered that Clause 10.3 only applied to sponsored attendance at meetings; not attendance based on a contracted service. This clause was therefore inapplicable to the patient agreement in this case and the Panel ruled **no breach of Clause 10.3**.

Overall

In relation to Clauses 5.1 and 2, whilst the Panel had ruled the sponsorship agreement to be a breach of Clause 8.3, the Panel bore in mind that the complainant had provided little detail and no reasons in support of their position. The complainant had not referred directly or indirectly to compliance nor to the requirements of Clause 5.1 or 2. It was not for the Panel to infer such matters on behalf of the complainant and the Panel did not consider that there were any other factors in this case to justify additional breaches of the Code. The Panel accordingly ruled **no breaches of Clause 5.1 and Clause 2**.

Complaint received 12 January 2025

Case completed 12 December 2025