

CASE AUTH/3833/10/23

CSL VIFOR

Voluntary admission in relation to an uncertified invitation to an overseas meeting

CASE SUMMARY

This voluntary admission related to an invitation sent by CSL Vifor’s global team to a UK health professional for its ‘Clinical Expert Exchange Meeting on CKD-associated pruritus’, the evening before for its symposium at a named European congress.

The outcome under the 2021 Code was:

Breach of Clause 5.1	Failing to maintain high standards
Breach of Clause 8.1	Failing to certify promotional material
Breach of Clause 8.2	Failing to certify events/meetings involving travel outside the UK UK
Breach of Clause 12.1	Failing to include prescribing information
Breach of Clause 12.9	Failing to include an adverse event reporting statement
Breach of Clause 12.10	Failing to include a black triangle

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

FULL CASE REPORT

A voluntary admission was received from CSL Vifor in relation to an uncertified email.

CSL VIFOR’S VOLUNTARY ADMISSION

“Background to the Issue:

Uncertified invite emailed to UK HCP by CSL Vifor UK:

The Global Medical Affairs team at Vifor (International) AG organised a ‘Clinical Expert Meeting’ at [named European congress]. On the 30th of March 2023, the international team approached the UK team to ask if there were any suitable UK HCPs who would be present at [named European congress] and would like to attend the internationally lead meeting.

A CSL Vifor UK employee contacted a UK HCP on 3rd April 2023 to gauge their interest in attending the 'Clinical Expert Meeting'. The CSL Vifor UK employee sent an email to the UK HCP using the following text, which they stated was a 'save the date' message rather than an invitation.

CSL Vifor - invitation to attend dinner at [named European congress]

I hope you're well. I wanted to ask if you will be attending the [named European congress] conference in Milan this year, and if you are, whether you would be interested in attending an evening dinner that my CSL Vifor Global colleagues are organizing.

The exact date will be confirmed in the next few days. However, there will be a 30 minute welcome and update on activities relating to CKDaP at 1830 followed by the dinner. In attendance will be leading clinicians with a special interest in this therapy area from across Europe.

It would be great if you are able to attend. I look forward to hearing from you.

Uncertified email sent to UK HCP by CSL Vifor International:

A UK based [medical employee] became aware around 31st March 2023 that a representative of CSL Vifor International had invited a UK HCP to attend "Clinical Expert Meeting" without prior certification of the activity or the invitation (but did not have full oversight of the meeting). Despite being fully aware of ABPI code, did not at the time ask for more details.

A CSL Vifor International employee had sent a formal invitation to a UK HCP on 12th April 2023 about Real world experience sharing on CKD-aP and its treatment clinical exchange meeting on which was to be held on the 16th June 2023 in the body of the email (no CSL Vifor medicines mentioned on the invite/agenda, but implied treatments were going to be discussed). Attached to the invitation was a flyer for CSL Vifor International's symposium 'Patient centered care in dialysis: Lets tackle CKD- associated pruritus' scheduled on 17th June 2023. The flyer mentioned CSL Vifor medicines and would be considered promotional by Vifor UK under the ABPI Code of Practice.

CSL Vifor UK's [head office employee] was made aware of the situation later and requested that the above-mentioned employee obtained further details of the meeting from the international team to ascertain what steps and sign off would be needed. The employee asked the global team on 24th April 2023, and another UK employee asked for details on 10th May 2023 when they had not received a reply from the international team.

Due to lack of information provided, this was escalated to the UK [senior medical employee] (new and interim) on 7th June 2023 where corrective actions were put in place.

Corrective Actions:

The 'invite for the CKD-aP real world experience sharing meeting was retracted on 8th June 2023.

CSL Vifor UK worked with CSL Vifor International to produce an invitation that complied with the ABPI Code of Practice and local SOPs/Processes, the invite was certified and

included all mandatory information. This certified invite was issued to the UK HCP on 14th June 2023.

CSL Vifor Pharma UK's policy is that all activities involving UK HCPs need to be reviewed and certified by the UK organization in advance, including invitations to be sent to UK-based HCPs.

Investigation:

A review has been undertaken by the CSL Enterprise Risk, Ethics and Compliance (EREC) team, Vifor's parent company. The output from that review is attached to this letter. [Description of investigation].

Preventative actions:

The [senior medical employee] produced a briefing/guidance document detailing the ABPI Code of Practice requirements for overseas meetings which was shared with the UK CSL Vifor team on 16th August 2023.

The CSL Vifor UK Medical team was trained by the [senior medical employee] about overseas meetings on 7th July 2023

The International teams have also received training on the ABPI Code of Practice requirements delivered by the UK Compliance Consultant. This training was provided on the following dates; 10th July, 18th July, 17th August 2023

Breaches:

Regrettably, Vifor UK believe that due to details outlined above that the following clauses have been breached:

- Clause 8.1 'Promotional material must not be issued unless its final form, to which no subsequent amendments will be made, has been certified by one person on behalf of the company in the manner provided for by this clause'
- Clause 12.1 'The prescribing information listed in Clause 12.2 must be provided in a clear and legible manner in all promotional material for a medicine except for abbreviated advertisements. The prescribing information must form part of the promotional material and must not be separate from it.'
- Clause 12.9 'All promotional material must include the prominent statement 'Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]'.
- Clause 12.10 'When required by the licensing authority, all promotional material must clearly show an inverted black equilateral triangle to denote that additional monitoring is required in relation to adverse reactions.'

Vifor Pharma UK understands the importance of maintaining high standards, hopefully this voluntary admission further demonstrates our commitment to the ABPI Code."

When writing to CSL Vifor, the PMCPA asked it to consider the requirements of Clauses 5.1, 8.1, 8.2, 12.1, 12.9 and 12.10 of the Code.

CSL VIFOR'S RESPONSE

The response from CSL Vifor is reproduced below:

"We have considered the additional clauses detailed by the PMCPA, and regrettably have concluded that our actions have not maintained high standards and thus we believe we have breached clause 5.1.

The Vifor International Medical Team had organised a 'Clinical Expert' meeting at the [named European congress]. The meeting arrangements were not certified by a UK final medical signatory, nor an appropriately qualified person as required by clause 8.2.

Therefore, regrettably we consider CSL Vifor UK to have breached clause 8.2.

CSL Vifor therefore voluntarily admit to having breached the below clauses:

- Clause 5.1
- Clause 8.1
- Clause 8.2
- Clause 12.1
- Clause 12.9
- Clause 12.10."

PANEL RULING

This voluntary admission related to an invitation sent by CSL Vifor's global team to a UK health professional for its 'Clinical Expert Exchange Meeting on CKD-associated pruritus' on 16 June 2023, the evening before for its symposium at the [named European congress].

CSL Vifor submitted that its UK employee emailed a UK health professional on 3 April 2023 to gauge their interest in the evening dinner event on 16 June following a request from global; an email invitation was subsequently sent to event attendees, including the UK health professional, on 12 April 2023 from a global employee who's email signature showed they were from the "CSL Vifor Difelikefalin team". The agenda for the event was titled "Real world experience sharing on CKD-aP and its treatment" which included "complimentary hospitality within the applicable meal limits" and attached to that email was a flyer for CSL Vifor International's symposium which would take place the following day. The attached flyer for the symposium included the title "Patient centered care in dialysis: Lets tackle CKD- associated pruritus" as well as the medicine 'difelikefalin' which appeared as part of the program for the symposium titled "An opportunity to improve CKD-associated Pruritus: sharing clinical experience of difelikefalin".

The Panel noted it was a well-established principle that pharmaceutical companies were responsible for the activities of overseas affiliates that came within the scope of the Code; in this regard, the Panel noted an email invitation had been sent by the global team to a UK health professional for an overseas meeting, which members of the UK company were aware of.

The Panel reviewed the contents of the email sent by CSL Vifor's global employee; both the body of the email along with its attachment made reference to Vifor's prescription only medicine difelikefalin and its indication CKD-associated pruritus, which, as acknowledged by Vifor, constituted promotion.

Noting that the invitation, consisting of the email and attached flyer, was promotional in its nature, the Panel considered that CSL Vifor had failed to certify the material as required by the Code prior to its issue and a **breach of Clause 8.1** was ruled, as acknowledged by CSL Vifor. The Panel further noted the omission of prescribing information and adverse event reporting statement along with the absence of an inverted black equilateral triangle to denote that additional monitoring was required in relation to adverse events for difelikefalin. The Panel therefore ruled a **breach of Clauses 12.1, 12.9 and 12.10**, as acknowledged by CSL Vifor.

While CSL Vifor submitted it had retracted and re-issued the certified invitation to the UK health professional, it was unclear whether the individual attended or whether there were other UK attendees present. Nonetheless, the Panel noted CSL Vifor's admission that the meeting arrangements were not certified by a UK final medical signatory, nor an appropriately qualified person and therefore ruled a **breach of Clause 8.2**, as acknowledged by CSL Vifor.

Clause 5.1 required that high standards must be maintained at all times.

CSL Vifor submitted that a UK based medical employee became aware around 31 March 2023 that a UK health professional had been sent an invitation to attend the meeting without prior certification of the activity or the invitation. The Panel queried the chronology of events submitted noting that this date pre-dated the emails sent to the UK health professional on 3 and 12 April. In any event, the Panel was concerned that the UK based medical employee did not ask for more details and that it was not until 7 June 2023 when matters were escalated to a UK senior medical employee following which corrective actions were put in place including retracting the material and re-issuing a certified invitation.

While the Panel took account of CSL Vifor's corrective and preventative actions, the Panel noted its rulings of breaches above and was concerned with the lack of action and subsequent urgency when UK employees were initially made aware of the matter; the Panel concluded that high standards had not been maintained and a **breach of Clause 5.1 was ruled**.

Voluntary admission received **9 October 2023**

Case completed **17 December 2024**