CASE AUTH/3689/8/22

VOLUNTARY ADMISSION BY CSL VIFOR

Promotional activities in relation to a Cardiology conference

CASE SUMMARY

This was a voluntary admission by CSL Vifor which related to certain promotional activities at a cardiology conference in May 2022 that had not been certified as required by the Code.

The Panel ruled a breach of the following Clauses of the 2021 Code as the promotional material in question had not been certified by a signatory notified in advance to the MHRA and PMCPA and therefore the promotional material had not been certified as required by the Code; certification underpinned self-regulation and the error was such that CSL Vifor had failed to maintain high standards:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 8.1	**Failing to certify promotional material**
Breach of Clause 8.4	**Failing to notify in advance to the PMCPA and the MHRA the names and qualifications of those nominated as signatories**

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

FULL CASE REPORT

CSL Vifor voluntarily admitted that certain promotional activities related to the European Society of Cardiology - Heart Failure Association (ESC - HFA) conference in May 2022 had not been certified as required by the Code.

As Paragraph 5.6 of the Constitution and Procedure required the Director to treat a voluntary admission as a complaint, the matter was taken up with CSL Vifor.

VOLUNTARY ADMISSION

Background to the Issue:
Vifor International AG engaged a third party to develop and host a multi-country online professional program hosted on Medscape.com. A copy of the Notice of Commission (NoC) dated 10 December 2021 was provided.

CSL Vifor stated that this voluntary admission was to transparently disclose an issue arising from an activity run by Vifor International during the European Society of Cardiology-Heart Failure Association (ESC - HFA) conference in May 2022. The activity in question was a banner sequence (5 banners) on the ESC-HFA 2022 congress website (and Medscape mobile apps)

relating to Ferinject (ferric carboxymaltose), which was organised and run by the third party. These banners were visible for a period of 60 days to health professionals visiting the congress website. When clicking on the banner, health professionals could see the Ferinject prescribing information as well as a link to the ESC Guidelines.

The banners developed for the ESC-HFA 2022 conference were included in the NoC, which contained a total of nine activities. The specific banner activity was listed under the “Conference Package” section of the NoC.

The banners were shown as a pop up on the ESC-HFA Website to 276,669 health professionals from around Europe, with about one fifth of the deliveries to UK health professionals. From this health professional group there were 275 clicks of which 57 were from UK health professionals.

All activities under the NoC (except for the Conference Package) specified a country list to define the target audience. The UK was not included in this country list and the NoC was intended to cover only the 11 countries that were listed.

CSL Vifor stated that the inclusion of the UK in the banner distribution was unintentional; it should have been restricted to health professionals from the 11 countries only, as was the case for the other eight activities set out in the NoC. Though the "Conference Package" section of the NoC referred to "Europe" rather than specific countries, all previous activities conducted under the arrangement with this third party had only been in the 11 countries listed above. On this occasion, the third party proceeded with a pan-Europe list without checking the target countries with Vifor International.

Vifor Pharma UK's policy is that all promotional materials presented to UK health professionals needed to be reviewed and certified by the UK organisation. CSL Vifor submitted that the only reason why it did not occur on this occasion was because neither Vifor International nor Vifor Pharma UK was aware that UK health professionals would have access to the promotional activity undertaken by the third party, as the UK was clearly out of scope for such activities.

ABPI Code:

CSL Vifor stated that on reviewing the banner ads, it considered that the messages were in line with the ABPI Code. The banners were reviewed and approved by Vifor International and therefore CSL Vifor did not believe that there had been a breach of Clause 8.1. However, since neither Vifor International nor Vifor Pharma UK was aware that those promotional materials would be accessible by UK health professionals, UK policies could not have been followed and as there was no certification of the banners by UK registered signatories, CSL Vifor submitted that it was transparently self-reporting the involuntary incident in consideration of Clause 5.1 and Clause 8.4 of the Code.

Investigation:
CSL Vifor stated that a review had been undertaken of the issue and areas of the approval process had been identified as requiring improvement.

In respect of the countries not within the scope of the NoC (such as the UK), the Conference Package section of the NoC stated "*the Conference Package will target the [third party] Network in Europe*", rather than specifying the countries. This was an involuntary drafting error in the NoC, but notwithstanding this, the third party should have been aware from discussions with the

Global team of Vifor International, as well as the other aspects of the NoC that the campaign was limited to the 11 countries which excluded the UK. The third party should have sought confirmation of the geographical scope of the campaign from Vifor International before it was launched, as all other promotional campaigns were limited only to those 11 countries in scope.

Corrective Action
CSL Vifor stated that as an immediate action, all activities with the third party in question and Medscape activities were immediately stopped as soon as the issue was identified and would not resume until remediation actions were fully implemented.

CSL Vifor stated that standard operating procedures would be put in place in order to implement an opt-in / opt-out process that would allow local affiliates to review promotional materials prepared by or on behalf of Vifor International's Global Marketing team for compliance under local rules that may apply. If the material did not comply with local rules following review by the relevant local affiliates, this country would be excluded from the campaign, or, where targeting was not possible, a statement would appear on the promotional material clearly stating that it was not intended for or suitable for health professionals from that particular country, and the relevant agencies notified that the material was not to be used in particular countries. The Veeva PromoMats system used by Vifor International, and its affiliates would be amended so local affiliates' decisions whether to opt-in or opt-out of a particular marketing campaign would be documented.

Vifor International was also in the process of reviewing all agreements with the third party and other digital marketing vendors and would revisit the terms and conditions to reflect the vendor's obligation to ensure that only countries that had expressly opted into a campaign were included in that campaign.

Training would be provided to relevant staff of local affiliates (and third-party vendors and agencies) regarding the opt-in / opt-out process before implementation of this system.

CSL Vifor stated that it understood the importance of maintaining high standards, and hoped this voluntary admission further demonstrated its commitment to the ABPI Code.

CSL Vifor was asked to provide the Authority with any further comments in relation to the requirements of Clauses 5.1, 8.1 and 8.4 of the 2021 Code.

RESPONSE

CSL Vifor stated that as per its voluntary admission, it considered that the materials in question were properly reviewed and approved at the global level following the procedures set forth in the relevant global SOP. However, as CSL Vifor was not aware that those materials could be accessed by health professionals in the UK, prior certification by a UK medical signatory had not been formally obtained as set forth in Clauses 8.1 and 8.4 of the ABPI code and that is why the issue had been self-reported as a demonstration of transparency. CSL Vifor submitted that it considered that the material in question was compliant in all other aspects with the UK code.

CSL Vifor submitted that despite the involuntary nature of this mistake, as CSL Vifor did not maintain high standards in terms of targeting the right audience for its promotional materials, it believed Clause 5.1 of the Code had been breached. As outlined in its voluntary admission,

CSL Vifor stated that it had investigated this incident and created appropriate corrective and preventive actions to remediate the issue and avoid reoccurrence.

PANEL RULING

The Panel noted CSL Vifor's admission that a Ferinject (ferric carboxymaltose) promotional banner sequence on the European Society of Cardiology - Heart Failure Association (ESC-HFA) 2022 congress website and Medscape mobile apps, available for 60 days to health professionals visiting the congress website, had not been certified by UK nominated signatories.

The Panel noted CSL Vifor's submission that the banners were shown as a pop up on the ESC-HFA Website to 276,669 health professionals from around Europe, with about one fifth of the deliveries to UK health professionals. From this health professional group, there were 275 clicks of which 57 were from UK health professionals.

The Panel noted CSL Vifor's submission that there was no certification of the promotional material in question by a registered nominated signatory for the UK.

Clause 8.4 of the Code stated that the names of those nominated as signatories as set out in Clauses 8.1 and 8.2, together with their qualifications, must be notified in advance to the Advertising Standards and Outreach Unit, Vigilance and Risk Management of Medicines Division of the Medicines and Healthcare products Regulatory Agency (MHRA), and to the Prescription Medicines Code of Practice Authority (PMCPA).

The Panel considered that as the names and qualifications of the person(s) who approved the material in question had not been notified in advance to the MHRA and PMCPA as required by the Code, **a breach of Clause 8.4 was ruled** as acknowledged by CSL Vifor.

In its initial letter informing the PMCPA of its voluntary admission, CSL Vifor stated:

> 'The banners were reviewed and approved by Vifor International and therefore we do not believe that there has been a breach of Clause 8.1'.

However, contrary to this, and following the case preparation manager's request for any further comments, the Panel noted that CSL Vifor subsequently submitted:

> 'However, as CSL Vifor was not aware that those materials could be accessed by healthcare professionals in the UK, prior certification by a UK medical signatory had not been formally obtained as set forth in the Clauses 8.1 and 8.4 of the ABPI code and that is why the issue has been self- reported as a demonstration of transparency.'

The Panel noted Clause 8.1 included:

> '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, subject to the provisions of the supplementary information to this clause where relevant. This person must be a registered medical practitioner or a pharmacist registered in the UK or alternatively, in the case of a product for dental use only, a UK registered dentist.'

The supplementary information to Clause 8.1 included that the registered medical practitioner should be capable of being registered in the UK without the need for additional tests of medical/clinical knowledge.

The Panel noted CSL Vifor's submission that the banners in question were reviewed and approved by Vifor International. However, it was not clear if the person(s) who reviewed and approved the material at Vifor International would meet the requirements of a signatory as set out in Clause 8.1 and its supplementary information.

Nonetheless, the Panel noted its ruling of a breach of Clause 8.4 above and considered that the promotional material in question had not been certified by a signatory notified in advance to the MHRA and PMCPA and therefore the promotional material had not been certified as required by the Code. The Panel thus ruled **a breach of Clause 8.1.**

The Panel noted CSL Vifor's submission that the banners developed for the conference were included in the Notice of Commission (NoC) between Vifor International AG and its third party. The NoC contained nine activities with the banner activity in question listed under the "Conference Package" section. The Panel further noted CSL Vifor's submission that the inclusion of the UK in the banner distribution was an unintentional error as it should have been restricted to health professionals from the 11 countries listed (which did not include UK), as was the case for the other eight activities set out in the NoC. The "Conference Package" section of the NoC stated it would target the third party's network in Europe, rather than specifying the 11 countries, which was, according CSL Vifor's investigation, an involuntary drafting error in the NoC.

The Panel considered that it was unfortunate that the drafting error in the NoC had occurred and that promotional Ferinject material had been made available to UK health professionals without being certified as required by the Code.

Whilst the Panel queried CSL Vifor's submission that the material in question was compliant in all other aspects with the UK code, it noted that the content of the material was not the subject of the voluntary admission and therefore the Panel made no assessment or rulings in this regard.

The Panel considered that certification underpinned self-regulation. The Panel was concerned that promotional material had been made available to UK health professionals without CSL Vifor UK's knowledge or approval. It was an established principle that UK companies were responsible for the acts and omissions of overseas affiliates for activity within the scope of the ABPI Code. The Panel considered that the error was such that CSL Vifor had failed to maintain high standards **and a breach of Clause 5.1 was ruled** as acknowledged by CSL Vifor.

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Complaint received **5 September 2022**

Case completed **30 August 2023**