CASE/0283/09/24

COMPLAINANT v AMARIN

Allegation regarding a company funded symposium

CASE SUMMARY

This case was in relation to a symposium at a conference held in London. The complainant made a number of allegations. The Panel considered that, key to these allegations, was the suggestion that the symposium was promotional for Amarin's medicine, Vazkepa (icosapent ethyl) despite having been funded through an unrestricted grant and treated as non-promotional.

The outcome under the 2021 Code was:

Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 12.1	**Failing to include prescribing information**
Breach of Clause 15.6	**Disguising promotional material or activities**
Breach of Clause 23.1	**Failing to meet the requirement that donations are freely given for the purpose of supporting healthcare with no consequent obligation on the recipient organisation to provide goods or services to the benefit of the pharmaceutical company in return**

No Breach of Clause 2	**Requirement that activities or materials must not bring discredit upon, or reduce confidence in, the pharmaceutical industry**

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 Amarin UK Limited was received from an anonymous, contactable complainant who described themselves as a health professional.

COMPLAINT

The complaint wording is reproduced below:

> "[Named conference] London Symposium 3:15 PM to 4:PM The company says they provide grant for a symposium. The content of symposium was heavily biased towards EPA a product of the company. There was no disclosure on the promotional nature of the meeting No prescribing information Wrong disclaimers on page 1. The company

has carried out disguised promotional activity in the name of unrestricted grant. Every aspect of the activity is promotional with heavy focus only on EPA. Two topics including headline of the meeting says EPA. I am surprised how company can provide grant to such a meeting. What is the process to get establish grant has been provided to true scientific activity rather than disguised promotion. The company has therefore brought discredit to entire pharmaceutical industry. It also shows very poor knowledge of UK compliance in such big conference."

When writing to Amarin, the PMCPA asked it to consider the requirements of Clauses 2, 5.1, 12.1, 15.6 and 23.1 of the 2021 Code.

AMARIN'S RESPONSE

The response from Amarin is reproduced below:

"Thank you for your letter dated 2 September 2024 to Amarin UK Limited regarding an anonymous complaint from a healthcare professional to the PMCPA about a symposium funded by Amarin.

We are committed to ensuring that all of our UK activities comply with the ABPI Code of Practice and Human Medicines Regulations 2012.

We have set out our response to the matters raised in the complaint below including, as requested, details of how the material was used, Amarin's involvement, how the event was funded, how attendees were invited, whether UK HCPs were permitted to attend and if any attended:

- Amarin's Global team received an unsolicited request from [named organisation] for an unrestricted grant to support an educational symposium at the [named conference] on [date] August 2024 titled "Clinical scenarios addressing residual risk in ASCVD: Understanding the role of triglycerides and EPA". [Named organisation] is a [named accreditation organisation] accredited independent third party providing continuing medical education in the cardiovascular field for healthcare professionals. A copy of [named organisation's] request and [named organisation's] accreditation statement is enclosed.

- The goal of the education symposium was stated in the request as being to provide "cardiovascular physicians with a state-of-the art update on the evolving role of icosapent ethyl, based on accumulating evidence, insights in the management of residual CV risk in patients on statin therapy and exchange of international experience:
    - Establish the role of triglycerides as marker [sic] for residual cardiovascular risk;
    - Apply recent clinical trial evidence of EPA on a case-by-case basis for patients with established CVD who are on statins and at risk of further CV events;
    - Identify barriers to the implementation of effective, long-term management of ASCVD;

- Provide practical guidance for day to day lipid management in patients with ASCVD".

- Amarin's Global team reviewed the request and liaised with Amarin UK in line with its Global Funding Management Policy and SOP on Medical Educational Grants and Third-Party Educational Program Grants (copies of which are enclosed). In accordance with the Policy and SOP, the review and approval process was led by Amarin's Medical Affairs team with no commercial involvement and the request was evaluated on objective criteria as a bona fide, independent, balanced and scientifically rigorous educational symposium provided by an established, accredited medical education provider that would benefit HCP's medical knowledge. The request was approved as an unrestricted grant for a non-promotional educational symposium by an [named accreditation organisation] accredited CME provider and on the basis that Amarin would have no involvement in the symposium.

- A written agreement was put in place between Amarin Pharmaceuticals Ireland Limited and [named organisation] prior to distribution of the grant to the recipient. The agreement stated clearly that the activity for which the grant is provided is for "scientific and educational purposes only and will not promote Amarin's product, directly or indirectly", "The activity will be independent, with a non-promotional purpose" and "If Amarin products are mentioned in the course of this activity, the Grant Recipient(s) will ensure that data regarding Amarin's products (and competing product) are made in accordance with all applicable laws, regulations and ethical rules and objectively selected and presented, with all full and fair disclosures including fair balance". The agreement also stated that Amarin would have no involvement in the session, including "Amarin will not control in any way the planning, content, speaker/moderator selection, or execution of any activity that is funded pursuant to this Letter of Agreement" and "Amarin will have no intervention or influence in the content of the activity".

- In line with the grant agreement, Amarin had no involvement at all with the symposium other than providing the unrestricted grant from Amarin's Global Medical department budget; Amarin did not select the topic or presenters, had no role in the development of the content, did not review or certify any of the content or related materials, did not brief any of the speakers and did not invite any UK attendees. The arrangement was entirely at arms' length. Amarin therefore did not certify the symposium materials and no speaker briefings were provided.

- The educational purpose of the symposium was reflected in the content comprised of four 5-10 minute presentations by four HCPs on "Introduction: A clinical case of a patient with ASCVD and high triglyceride levels", "Understanding the role of triglycerides in the assessment of residual risk", "Managing a patient with residual risk: Applying recent evidence with EPA to practice" and "Integrating EPA in CV risk reduction strategies: Practical experience and guidance" followed by audience discussion and concluding with "take home" messages by one of the HCPs. The topics and content were accepted by [conference organiser's] scientific committee for an educational symposium.

- Attendees were invited to the symposium by [named organisation]. Amarin had no involvement in inviting UK attendees and did not distribute any flyers for the symposium. Amarin representatives who were present in a separate part of the [named] Conference were not briefed on the symposium.

- The symposium was attended by HCPs participating in the [named] conference, which included both UK and non-UK HCPs.

- Amarin's involvement in the funding of the symposium was made clear and not disguised throughout. The nature of Amarin's involvement was stated on the symposium flyer, programme and slides: "Supported by an unrestricted educational grant from Amarin. The scientific programme has not been influenced in any way by its sponsor". The educational intention of the symposium and the fact that EPA would form part of the discussion was indicated in the symposium flyer and programme.

- Subsequent to the approval of the educational grant, shortly before the symposium Amarin UK noted the possibility that some content of the symposium might be regarded as promotional, as Amarin's VAZKEPA® (icosapent ethyl) product is a form of the ethyl ester of EPA (eicosapentaenoice [*sic*] acid). As Amarin had no involvement in the development of the materials and did not have a copy of the presentation materials at any time prior to the symposium, and the agreement with [named organisation] made clear that the content was to be educational and non-promotional, Amarin was not in a position to confirm this. Taking a prudent approach, Amarin asked [named organisation] to include a disclaimer directed to UK HCPs on the symposium materials and in the presentation that it may contain promotional content and that prescribing information was available. [Named organisation] included a disclaimer ""For UK Healthcare Professionals, please see separate disclaimer*" and "*This meeting may contain certain promotional materials. Prescribing information will be available at the meeting" on the symposium programme, however an earlier version of the flyer was used by [named organisation] which did not contain this disclaimer. The additional disclaimer was also referenced in the introductory presentation deck. We understand from [named organisation] that due to a technical issue, the slide was not displayed to the audience during the presentation but the declaration of Amarin's involvement was communicated verbally at the start of the session, as evidenced in the video recording of the symposium enclosed.

- As can be seen from the slides and video recording, the brand name of Amarin's product VAZKEPA® was not discussed, in line with the grant agreement.

While Amarin acknowledges the additional sensitivity of an educational symposium where a moiety for which Amarin has a related licensed product is discussed, on balance the symposium was non-promotional as intended under the grant request and as set out in the grant agreement. It met a bona fide need for education for clinicians in relation to ASCVD, triglycerides and EPA as identified by [named organisation] and

was developed independently by [named organisation] without any involvement from Amarin.

In relation to the specific clauses of the Code referenced in your letter:

- **Clauses 12.1:** The symposium material was non-promotional material produced by [named organisation] without any involvement from Amarin and therefore no prescribing information was included by [named organisation] but was available to attendees on request.

- **Clause 15.6:** The symposium was educational and non-promotional and Amarin's involvement in providing an unrestricted educational grant to support the symposium was made clear on the symposium materials and at the start of the symposium.

- **Clause 23.1:** The grant was provided for the purpose of supporting education with no obligation on the recipient organization to provide anything to the benefit of Amarin in return. Amarin's provision of the educational grant was made clear to the attending audience.

- **Clauses 2 and 5.1:** The provision of an unrestricted grant to an accredited independent third party medical educational provider to support an educational symposium with which Amarin had no other involvement complied with the Code. We therefore believe this does not warrant a finding of breach of Clause 2 or 5.1.

We hope this addresses the points raised in the complaint and your letter. If you have any questions, please do not hesitate to contact me."

PANEL RULING

This complaint was about a symposium at the conference of a European society, held in London in August 2024. The complainant made a number of allegations. The Panel considered that, key to these allegations, was the suggestion that the symposium was promotional for Amarin's medicine, Vazkepa (icosapent ethyl) despite having been funded through an unrestricted grant and treated as non-promotional. The Panel noted that icosapent ethyl was a stable ethyl ester of the omega-3 fatty acid, eicosapentaenoic acid (EPA) and that it was a black triangle medicine that was subject to additional monitoring.

Amarin submitted that it received an unsolicited request from an accredited medical education provider for an unrestricted grant to support an educational symposium titled "Clinical scenarios addressing residual risk in ASCVD: Understanding the role of triglycerides and EPA". Amarin submitted that the request was reviewed by its Global team, liaising with Amarin UK. The request was approved as an unrestricted grant for a non-promotional educational symposium by an accredited continuous medical education (CME) provider and on the basis that Amarin would have no involvement in the symposium. Amarin submitted that the arrangement was entirely at arm's length.

The complainant alleged that:

- the content of the symposium was heavily biased towards EPA;

- there was no disclosure of the promotional nature of the meeting;
- this disguised promotional activity was carried out in the name of an unrestricted grant;
- there were "wrong disclaimers on page 1" (the complainant provided photographs of the symposium programme document);
- there was no prescribing information;
- the company showed poor knowledge of UK compliance and had brought discredit upon the pharmaceutical industry.

The Panel considered that the first two questions to be addressed were whether the arrangements had been arm's length and whether the symposium was promotional.

Were the arrangements for the symposium 'arm's-length'?

The Panel noted that it was possible for a company to provide funding for activities or materials produced by an independent organisation which mentioned its own products and not be liable under the Code for its contents, but only if there had been a strictly arm's-length arrangement between the parties.

The Panel took into account the content of the grant request form, including (emphasis added by the Panel):

- The title of the request was:

  "Clinical scenario's [*sic*] addressing residual risk: Understanding the role of triglycerides and **EPA**"

- The introduction to the request stated:

  "This is a request for funding by an educational grant for the development and implementation of a satellite symposium focussed on the e [*sic*] **role of novel therapies such [as] Icosapent ethyl** in the management of residual cardiovascular risk …"

- The initiative goal was described as:

  "The overall objective of the learning is to provide our database of cardiovascular physicians with a state-of-the-art **update on the evolving role of icosapent ethyl**, based on accumulating evidence, insights in the management of residual CV risk in patients on statin therapy and exchange of international experience:
  - Establish the role of triglycerides as a marker for residual cardiovascular risk
  - Apply **recent clinical trial evidence of EPA** on a case-by-case basis for patients with established CVD who are on statins and at risk of further CV events
  - Identify barriers to the implementation of effective, long-term management of ASCVD
  - Provide practical guidance for day to day lipid management in patients with ASCVD"

- The rationale section of the grant request form included:

  "**Recent trials, such as REDUCE-IT** [(Reduction of Cardiovascular Events with Icosapent Ethyl–Intervention Trial)] have demonstrated efficacy for lowering triglyceride

levels but also lowering the risk on the primary composite end point of cardiovascular death, nonfatal myocardial infarction, nonfatal stroke, coronary revascularization, or unstable angina, assessed in a time-to-event analysis.
This result is considered to stand apart from the negative findings of several contemporary trials of other agents that also lower triglyceride levels, including other n-3 fatty acids, extended-release niacin, fenofibrate, cholesteryl ester transfer protein inhibitors and recently pemafribrate in the PROMINENT trial."

and:

"**With icosapent-ethyl now available for physicians in several European countries** it becomes crucial to provide the medical community with state of the art updates, opinion and perspectives by sharing and exchanging international experience."

- The grant request form included a list of four health professionals, labelled as "Suggested Faculty of the symposium: *(**to be discussed**/decided)*

- The four proposed agenda topics included: "Integrating **icosapent** in CV risk reduction strategies: Practical experience and guidance"

- The budget breakdown included a line for "**Outcomes reporting**" and the funding request included details of the metrics that would be collected and reported in relation to the online hosting of the symposium recording:

  "… we will **report on reach, level of engagement, profile of participants, impact on knowledge and practice** …

  For this program we will **guarantee a minimum** of 5.800 learners …"

The Panel also took into account the wording of the grant funding agreement, which included the following statements:

- "The activity is for scientific and educational purposes only and will not promote Amarin's product, directly or indirectly." [within Point 1]

- "Amarin will not control in any way the planning, content, speaker/moderator selection, or execution of any activity that is funded pursuant to this Letter of Agreement." [within Point 2]

- "Amarin will have no intervention or influence in the content of the activity." [within Point 4]

- "Amarin will be allowed to **send up to 4 attendees** to testify and confirm the educational nature of the activity." [within Point 4]

- "The activity will be independent, with a non-promotional purpose, and free from commercial influence or bias." [within Point 5]

- “The title of the activity will fairly and accurately represent the scope of the presentation.” [within Point 5]

- “The activity will present discussion of multiple treatment options and will not focus on a single product.” [within Point 5]

The Panel noted that there appeared to be some conflict between statements in the funding agreement and the objectives of the symposium outlined in the grant request form, which was included at the end of the funding agreement document. As the grant request form formed part of the funding agreement document, the Panel determined that it had not been superseded and remained relevant at the point at which the funding agreement was signed.

The Panel queried what was meant by “to be discussed/decided” in relation to the list of potential speakers and whether this meant that Amarin was involved in their selection. The Panel noted that Amarin was at least aware of potential speakers when deciding to fund the symposium.

In relation to the reporting requirements outlined in the funding request form, the Panel considered that there was a difference between undertaking due diligence to ensure that funds were used for the intended purpose and the detailed reports which formed part of the funding agreement (with its own line in the budget breakdown) in this case.

In the Panel’s view, Amarin would have had a clear idea of what would be covered in the symposium before deciding whether or not to fund it. The Panel considered that Amarin would have been aware that icosapent ethyl would be covered positively within the symposium, including being the primary medicinal treatment discussed. In the Panel’s view, prior awareness that the symposium would mainly discuss the company’s medicine, and the receipt of benefits such as detailed reports containing analytical data, meant the arrangements were not strictly arm’s length.

The Panel determined that the arrangements between Amarin and the medical education provider in relation to the symposium at issue had not been strictly arm’s-length; therefore, Amarin was considered liable for the activity under the Code.

Was the symposium promotional for Vazkepa?

The Panel noted Amarin’s submission that the symposium was educational and accredited by a European accrediting body. In the Panel’s view, however, this did not mean that the symposium was necessarily non-promotional as defined by the Code: promotional meetings must also have clear educational content and all information must be fair and balanced. The Panel also noted that it was an established principle under the Code that a medicine can be promoted without its name being mentioned.

The Panel noted Amarin’s submission that, subsequent to the approval of the grant and shortly before the symposium, it asked the medical education provider to include a disclaimer directed to UK health professionals stating that the symposium may contain promotional content and that prescribing material was available.

In the Panel's view, the symposium was promotional for Amarin's medicine, Vazkepa (icosapent ethyl), a form of the ethyl ester of EPA. In reaching this determination, the Panel took into account the following:

- It was clear from the grant request form that EPA and icosapent ethyl would be discussed during the symposium (see comments above)

- The title of the symposium mentioned EPA: "Clinical scenarios addressing residual risk in ASCVD: Understanding the role of triglycerides and EPA"

- The imagery on the symposium programme and flyer included the chemical structure of EPA

- The educational objectives listed on the programme and flyer were the same as those in the grant request form (above) and mentioned EPA

- The symposium programme stated "This meeting may contain certain promotional materials. Prescribing information will be available at the meeting."

- The symposium agenda was split into six sections, two of which mentioned EPA in the title:
    - "Introduction: A clinical case of a patient with ASCVD and high triglyceride levels"
    - "Understanding the role of triglycerides in the assessment of residual risk"
    - "Managing a patient with residual risk: Applying recent evidence with EPA to practice"
    - "Integrating EPA in CV risk reduction strategies: Practical experience and guidance"
    - "Discussion: 5 burning questions from the audience"
    - "The 5 key take home messages"

- The second speaker referred to icosapent ethyl at the end of their presentation, stating: "… icosapent ethyl does reduce the number of atherogenic lipoproteins but also has significant impact on inflammatory components …"

- The third speaker's presentation (16 slides in total) was particularly focused on icosapent ethyl, including nine slides focused on the REDUCE-IT clinical trial, with a specific slide on the key efficacy findings, and one slide on a validation study. The Panel particularly noted the following comments made by the speaker in relation to a slide showing the reduction in recurrent and total ischaemic events (icosapent ethyl vs placebo):
  "When we think about health economics, those curves that I was showing you show you the time to first event – but many of these people will have recurrent events. So, from a health economic perspective, those benefits in absolute terms are huge when you look at the […] recurrent events prevented. But remember you're actually hampering yourself with this type of analysis when you think about the benefit. If you are reducing cardiovascular death, you are potentially making people more at risk (because they're living longer) for those other non-fatal events. So, if you like, this is an underestimate of the true benefit of this treatment."
  The speaker also described a meta-analysis of Omega-3 trials:

"… If you synthesise the totality of the data, what you basically can see is those trials that used icosapent ethyl give you this consistent benefit and when you look at trials, and there are many more of those, that used a mixture of EPA and DHA – so the two different forms of Omega-3 – that mixture does not appear to give you the same benefit."
In their concluding slide, the speaker went on to say:
"Icosapent ethyl, particularly at a dose of 4g daily, appears to not only reduce cardiovascular events but multiple events, so it is likely to be a lot more cost effective than we think. We see this excess [risk] of atrial fibrillation, it's relatively modest, but no excess risk of strokes."

- The slides for the fourth section of the symposium were titled "Integrating icosapent in CV risk reduction strategies: practical experience and guidance" and focused on the "guidelines to practice gap"; they included, among other things, a slide on the NICE Technology Appraisal for icosapent ethyl and a slide on the mechanism of action of icosapent ethyl

Addressing the complainant's specific allegations

Having determined that the arrangements for the symposium were not strictly arm's length and that the symposium was promotional for Amarin's medicine, the Panel considered the complainant's specific allegations.

The complainant alleged that there was no disclosure of the promotional nature of the meeting and that Amarin had carried out disguised promotional activity in the name of an unrestricted grant.

Clause 23.1 of the Code stated that donations and grants are funds, benefits-in-kind or services freely given for the purpose of supporting healthcare, scientific research or education, with no consequent obligation on the recipient organisation, institution and the like to provide goods or services to the benefit of the pharmaceutical company in return.

In the Panel's view, the requirements of Clause 23.1 in relation to the definition of a grant had not been met. The Panel considered that because it was clear from the grant request form that the symposium would feature Amarin's medicine prominently and in a favourable light, and because the recipient organisation had guaranteed (within the grant request form) a minimum number of learners and to provide detailed reports, there was effectively an obligation on the recipient organisation to provide a symposium that was to the benefit of Amarin. The Panel ruled a **breach of Clause 23.1**.

Regarding the allegation that there was no disclosure of the promotional nature of the symposium (that it was "disguised") and that there were "wrong disclaimers on page 1", the Panel took into account Amarin's submission that it had, after the approval of the grant and shortly before the symposium, noted the possibility that some content of the symposium might be regarded as promotional and had asked for a disclaimer directed to UK health professionals to be included on the symposium materials and in the presentation. Amarin submitted that this disclaimer ("For UK Healthcare Professionals, please see separate disclaimer*" and "*This meeting may contain certain promotional materials. Prescribing information will be available at the meeting") was included on the symposium programme but that it had been omitted from the flyer. Amarin submitted that the disclaimer had been included in the introductory slides but that

the slide with this information was not displayed on the day. Amarin submitted that the declaration of Amarin's involvement was communicated verbally at the start of the session.

From the materials provided by Amarin and the complainant, the Panel observed that:

- The symposium programme included the following statement in a blue box at the bottom of page 1:

  This CME accredited program is funded by an unrestricted educational grant from Amarin and is intended for Healthcare Professionals outside the UK only. For UK Healthcare Professionals, please see separate disclaimer*.Amarin have not influenced or been involved with the development of the content this the programme.

  Beneath the blue box was the following text:

  "In compliance with [named accreditation organisation] guidelines, all speakers/chairpersons participating in this programme have disclosed or indicated potential conflicts of interest which might cause a bias in the presentations. The Organising Committee/Course Director is responsible for ensuring that all potential conflicts of interest relevant to the event are declared to the audience prior to the CME activities." *This meeting may contain certain promotional materials. Prescribing information will be available at the meeting.

- The symposium flyer included the following statement in a blue box at the bottom of page 1:

  This CME accredited program is funded by an unrestricted educational grant from Amarin and is intended for Healthcare Professionals outside the UK only. For UK Healthcare Professionals, please see separate disclaimer. Amarin have not influenced or been involved with the development of the content this the programme.

  Beneath the blue box was the following text:

  "In compliance with [named accreditation organisation] guidelines, all speakers/chairpersons participating in this programme have disclosed or indicated potential conflicts of interest which might cause a bias in the presentations. The Organising Committee/Course Director is responsible for ensuring that all potential conflicts of interest relevant to the event are declared to the audience prior to the CME activities."

- Slide one of the introductory presentation included the following statement in the bottom left corner:

  Supported by an unrestricted educational grant from Amarin

- Slide four of the introductory presentation included the following statement below information about the CME accreditation:

  Supported by an unrestricted educational grant from Amarin and the following statement in a blue box on the right-hand side of the slide:

  For UK Healthcare Professionals, please see separate disclaimer* Amarin have not influenced or been involved with the development of the content this the programme

- From the video recording of the symposium (and Amarin's submission), it appeared that the first few slides of the introductory presentation were not presented; the speaker stated: "Welcome, everybody, to this satellite symposium entitled 'Clinical scenarios

addressing residual risk in ASCVD: understanding the role of triglycerides and EPA'. This is an [named accreditation organisation]- accredited satellite symposium. It is supported by an unrestricted grant from Amarin which was not involved in the design or content of the programme."

- There were no such disclaimers present in the slides for the other sections of the symposium and the speakers made no verbal statements regarding either Amarin's involvement or the promotional nature of the symposium.

The Panel concluded that the statement about promotional content was only present on the symposium programme document. The flyer and the introductory slide included only part of the statement that Amarin had requested, referring the reader to a footnote that was not present. None of the speakers made reference to the symposium containing promotional information.

The Panel had concerns about the wording of the declaration of Amarin's involvement. The Panel firstly queried the practicalities of excluding UK health professionals from a symposium held in London, and then noted the ambiguity of the disclaimer appearing to both exclude UK health professionals and also to provide a separate disclaimer for them. In the Panel's view, it was not clear to the reader whether UK health professionals should attend the symposium or not. Regardless of whether UK health professionals attended, the symposium would be subject to the ABPI Code as it took place in London.

The Panel was also concerned about the prominence of the declaration of involvement, which was at the bottom of the symposium programme and flyer, in very small font. The Panel noted the requirements of Clauses 5.5, 10.9 and 25.3 in relation to the declaration of involvement being unambiguous and sufficiently prominent that readers are aware of the company's involvement at the outset.

The Panel noted that the case preparation manager had not raised Clauses 5.5, 10.9 or 25.3 in relation to the complainant's allegations and so considered its observations above in terms of the requirement of Clause 15.6 that promotional material and activities must not be disguised.

In the Panel's view, it would not be clear to attendees that the symposium would contain promotional content. The statement on the symposium programme was unclear in this regard and there was no such statement present on other materials, including the invitation flyer, or made verbally at the start of the symposium. The Panel therefore ruled a **breach of Clause 15.6**.

The complainant alleged that there was "no prescribing information". Amarin submitted that prescribing information was available to attendees on request.

Clause 12.1 of the 2021 Code required that the prescribing information must be provided in a clear and legible manner in all promotional material for a medicine (except for abbreviated adverts) and must form part of the promotional material and must not be separate from it. Clause 12.5 provided that, in audiovisual material, the prescribing information may be provided either by way of a document which is made available to all persons to whom the material is shown or sent, or by inclusion in the audiovisual material itself.

The Panel took into account its observations above that the only reference to the availability of prescribing information was on the symposium programme in very small font. There was no

reference made to the availability of the prescribing information in any of the speakers' slides, nor was it mentioned verbally during the symposium.

The Panel considered that the requirements of Clause 12.1 had not been met. The Panel ruled a **breach of Clause 12.1**.

The complainant alleged that Amarin had showed poor knowledge of UK compliance and had brought discredit upon the pharmaceutical industry.

The Panel considered that transparency was an important means of building and maintaining confidence in the industry. The Panel considered that the disguised promotion of Vazkepa meant that high standards had not been maintained. The Panel ruled a **breach of Clause 5.1**.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel was concerned that, although Amarin UK was consulted by its global colleagues, the company had not identified that the activity constituted promotion; however, there was no evidence that Amarin had influenced the content that was presented. The Panel considered that the matters raised by the complainant were adequately covered by its rulings above and did not consider that a breach of Clause 2 was warranted. The Panel therefore ruled **no breach of Clause 2**.

Complaint received **31 August 2024**

Case completed **23 September 2025**