CASE/0292/09/24

COMPLAINANT v ASTRAZENECA

Allegations about a symposium at a congress

CASE SUMMARY

This case was in relation to an AstraZeneca sponsored symposium which was held at an international congress in London in September 2024. It was alleged that the symposium, on cardiac amyloidosis, included data from incomplete or ongoing clinical trials and AstraZeneca's involvement was not clear to attendees.

The outcome under the 2021 Code was:

Breach of Clause 3.1	**Promoting a medicine prior to the grant of its marketing authorisation**
Breach of Clause 5.1	**Failing to maintain high standards**
Breach of Clause 5.5	**Failing to be sufficiently clear as to the company's role and involvement**

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 AstraZeneca UK Limited was received from an anonymous, non-contactable complainant who described themselves as a cardiologist.

COMPLAINT

The complaint wording is reproduced below with some typographical errors corrected:

> "I am a cardiologist working in heart failure and have had interactions with these drug companies in recent times regarding their developments in the field of TTR [transthyretin] cardiac amyloidosis. I was surprised to see at the recent [named international congress], held in London, that each of these companies conducted sponsored symposia on the field of cardiac amyloidosis and included data and information on their trials that are either complete or ongoing in this field. It is my understanding that this is not acceptable and is considered promotion, and I am unclear how they can promote their drugs in this way when they haven't been reviewed by the MHRA? The same speakers more or less spoke at each of these sessions and

there was a lot of discussion on which is the right treatment choice and which should be used first or in combination and my view is that we cannot make this judgement until we see their respective licences. AstraZeneca tried to distance themselves from their own symposia by running it via a third party, so you had to look carefully to realise they were behind it. It is great to see the advances in this much needed field of medicine, however I feel these companies have overstepped their mark in promoting their drugs before undergoing due process and review. Let us clinicians review the data and make our own judgements whilst the trials are ongoing before they start selling their drugs to us! I am remaining anonymous so as not to prejudice any future activity I may or may not do with these companies."

When writing to AstraZeneca, the PMCPA asked it to consider the requirements of Clauses 2, 3.1, 5.1 and 5.5 of the 2021 Code.

ASTRAZENECA'S RESPONSE

The response from AstraZeneca is reproduced below:

"Thank you for your letter dated 17 September 2024. As always, we are disappointed to receive a complaint concerning an independent symposium that AstraZeneca (AZ) supported via an 'arm's length' arrangement during the [named international congress].

For high level context, AZ received an unsolicited request for a financial grant from [named medical media company] to support a proposed educational symposium at [named international congress]. AZ provided funds to [named medical media company] in the form of a grant for healthcare professional education purposes – we wish to categorically state that AZ had no influence nor control over the symposium agenda, its content, the selection of speakers or any other part of its execution at the congress. [Named medical media company] was solely responsible for all of the above from its inception through to its complete execution.

Please find our detailed response to each of the complainant's allegations below.

ASTRAZENECA'S RESPONSE

Allegation 1:

AZ conducted a sponsored symposium on the field of cardiac amyloidosis, which included data and information on AZ trials that were either complete or ongoing in this field. **Therefore, promotion of eplontersen occurred prior to the grant of Marketing Authorisation**

An unsolicited grant request (to provide independent education at [named international congress] was made by [named medical media company] and three other organisations, via the AZ external funding website page.

For reference, [named medical media company] is a well-reputed company that provides education to healthcare professionals (HCPs) on all aspects of cardiovascular health and disease management. Prior to submitting the grant request, [named medical media company] verbally approached AZ's External Scientific Engagement team in

Global BioPharmaceuticals Medical to inquire as to whether AZ would be open to reviewing a grant request for a CME-accredited educational symposium at [named international congress]. AZ confirmed that this would be possible but would be subject to review and approval (in the same manner as all other Grants and Donations made by AstraZeneca). The proposed content of the symposium was not discussed. However, it was made clear to [named medical media company] that the grant would not cover the cost of procuring a symposium slot at the congress; AZ had already purchased several slots, one of which could be allocated to a requesting organisation whose grant application was successfully supported.

Subsequently, [named medical media company] submitted a financial grant request via the AZ external funding website for an independent, 60-minute CME (Continuing Medical Education) accredited symposium entitled 'The Bigger Picture: An expert assessment on the true impact of ATTR-CM'.

The symposium was fully-owned and executed by [named medical media company] in its entirety - AZ had no oversight, influence or input into the agenda, its content, development of materials, selection of speakers, or any other arrangements for the symposium.

Approval of the Grant Request

The AZ Global Medical Affairs Team and Global External Funding team reviewed the grant request from [named medical media company] and approved it for funding for the following reasons:

- The high educational value for HCPs attending the congress; the session would cover the unmet need and burden of the disease, awareness regarding the importance of timely diagnosis, as well as routine management of ATTR-CM.
- The activity would not promote AZ medicines - Eplontersen is currently in active Phase III clinical development to evaluate the efficacy and safety of the medicine in patients with ATTR-CM - there is currently no efficacy or safety data from the Phase III trial for Eplontersen in ATTR-CM. In addition, there are many medicines being investigated in this area. It was clear from the proposal and draft agenda that the symposium would not focus on any one medicine.
- The design, delivery and dissemination of the educational content is independent of AZ and would be fully controlled and owned by [named medical media company].
- The content would receive CME accreditation from the European Board for Accreditation of Continuing Education for Health Professionals (EBAC), which does not permit CME activities with commercial interest. Please note that this information on the CME accreditation was provided by [named medical media company] on the AZ grant submission platform and not in the proposal.

In the spirit of full transparency, we would like to disclose to the PMCPA that, following an investigation into the matter, it appears that the grant Letter of Agreement (LOA) was not certified at the time of approval. Rather, prior to the symposium itself, the LOA

was reviewed (via email) by a UK Nominated Signatory, who ensured that it met all the requirements of a grant, and that it was in line with the ABPI Code. As a result, AZ did provide an appropriate level of due diligence.

Following internal approval of the grant request, AZ communicated the successful approval of the grant application and requested [named medical media company] to complete the following actions:

- Use the disclaimer describing AZ involvement and
- Provide AZ with status updates, to ensure the grant funds had been utilised, as per the grant agreement.

It is important to state clearly at this point that AZ did not advertise the symposium in any way, nor did we invite anyone to attend it.

This was an independent educational grant provided to [named medical media company] by AZ and so AZ refute a breach of 3.1 on this allegation.

Allegation 2:

> **AZ tried to distance themselves from their own symposia by running it via a third party. It was not clear that AZ were involved in the symposium.**

AZ refutes this allegation. It was made clear in the congress programme and before and during the symposium that the meeting was led by [named medical media company], with funding support via a grant from AZ.

This is evidenced as follows:

1. **Online congress programme**: The declaration '*Industry session*' and '*Organised by* [named medical media company] *Medical Education. Supported by an unrestricted grant from AstraZeneca*' is stated on the [named international congress] online programme and on a page with further details of the symposium. The statement of declaration is not fully aligned to what was agreed with AZ, because [named international congress] has standard text which has to be utilised for industry sessions. Nonetheless it was clear at the outset that the session was supported by AZ.

2. **Symposium session**: At the beginning of the symposium (1 minute into the presentation), the first speaker stated, *'The session is supported by AstraZeneca, but they didn't have any impact or influence on content or choosing speakers*.' This is reflected in the online recording accessible for [named international congress] delegates, and so anyone who joined the session would have been informed of AZ's involvement of the session from the outset.

We refute the allegation that AZ was trying to distance itself from the symposium. AZ's involvement was made abundantly clear both before and during the symposium. Therefore, we deny a breach of Clause 5.5.

In addition, due to the reasons outlined above, AZ is confident that high standards have been maintained and we have not brought disrepute upon the industry. Therefore, we refute any breach of Clause 5.1 and 2.

SUMMARY

As stated above, this symposium was independently created and delivered by [named medical media company] with grant support from AZ. AZ had no influence or control over any aspect of the symposium, from its inception to its execution. Given the draft agenda shared with us in the proposal, the current development status of eplontersen in ATTR-CM and the absence of any data for eplontersen for ATTR-CM, we did not believe that providing a grant to [named medical media company] to provide education about ATTR-CM could result in promotion of eplontersen. Given the 'arm's length' nature of the arrangement, there could be no way for AZ to know what the content of the educational session planned by [named medical media company] would be. Finally, the nature of AZ's involvement was made abundantly clear from the outset, on the [named international congress] scientific program, and before and during the symposium itself, in line with [named international congress] regulations.

AstraZeneca takes its responsibilities under the ABPI Code very seriously. Based on the above detailed response, we **refute all allegations of breaches of clauses 2, 3.1, 5.1, 5.5.**"

PANEL RULING

This complaint concerned a symposium sponsored by AstraZeneca, held at an international congress in London in September 2024. It was alleged that the symposium, on cardiac amyloidosis, included data from incomplete or ongoing clinical trials. It was further alleged that AstraZeneca distanced themselves from the symposium by running it via a medical media company which meant their involvement was not clear to attendees.

AstraZeneca submitted that it had received an unsolicited request from a medical media company to support the educational symposium. AstraZeneca's position was that it had supported the activity at arm's length and that it provided funds in the form of a grant, based on the following conditions:

- that AstraZeneca had no influence or control over the symposium agenda, content or speakers,
- the high educational value of the symposium for health professionals,
- the content of the symposium would not include any promotion of AstraZeneca medicines, and
- the content of the symposium would be controlled by the medical media company.

The first matter for the Panel to consider was the nature of the arrangement between AstraZeneca and the media company.

The Panel bore in mind the definition of donations and grants at Clause 23.1 of the Code as:

> "*providing 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."

The Panel reviewed the contents of the grant proposal which requested funding to deliver a 60-minute symposium entitled "*The Bigger Picture: An expert assessment on the true impact of ATTR-CM [transthyretin amyloidosis-cardiac myopathy*]". The Panel observed that the learning objectives of the grant proposal included that physicians would be able to, among other things, "*list the advantages of emerging classes of agents being evaluated in ATTR-CM*". An overview of the proposal included the following beneath the heading regarding knowledge of current and future treatments:

> "*Other classes of drug with different modes of action are being evaluated in ATTR-CM, with silencers perhaps the closest to being approved, owing to their proven effectiveness in ATTR-PN [transthyretin amyloidosis-peripheral neuropathy). Since the majority of patients with ATTR-CM will develop cardiomyopathy, there is an urgent need for new treatments and for cardiologists to have knowledge of the clinical efficacy, particularly in patient populations with the highest unmet need, such as those with a mixed phenotype.*"

The draft agenda included the title, "*Where are we now and what's next in management? (10 mins)*"; beneath which were three bullet points that read:

- "*Effectives of currently approved therapies for ATTR-CM*
- *Overview of the most recent efficacy data*
- *Ongoing and future trials*
    - *Treatments*
    - *Imaging*"

The *Reporting & Programme Analysis* section of the grant proposal included that the media company would send a follow up survey after eight weeks to understand whether there had been any impact on daily clinical practice following the symposium. It outlined the following outcomes that would be delivered to AstraZeneca at intervals of one week, three months, five months and twelve months:

- Detailed reports with the number of video plays and engagement levels in the video
- The job function of physicians engaged in the content
- Number of CME credits issued
- Data from the surveys completed
- An outcomes-based presentation delivering insights into this programme nine months following the delivery of the symposium by the medical media company

The Panel queried whether the arrangement constituted a grant as classified by AstraZeneca. While the written agreement between the parties did not specify any deliverables or consequent obligations, it referred to the funding request letter which nonetheless set out the outcomes. In the Panel's view, the provision of detailed reports, which included physician role data amongst other things, and the outcomes-based presentation, went beyond due diligence.

The Panel further noted that it was possible for a company to not be liable under the Code for the contents of a symposium such as this, but only if there had been a strictly arm's length arrangement between the parties.

In practical terms, the arrangements must be such that there could be no possibility that the pharmaceutical company had been able to exert any influence or control over the final content of the material. PMCPA guidance on arm's length arrangements, updated in August 2025, included factors which might mean there had *not* been a strictly arm's length arrangement. These would include, but not be restricted to:

- Initiation of the material, or the concept for it, by the pharmaceutical company
- Awareness by the company prior to funding that the material would mainly discuss the company's medicine and/or positively position it above other treatments
- Influence from the pharmaceutical company on the content/balance/scope of the material. (Note: Correction of factual inaccuracies alone is not enough to compromise an arms-length arrangement, so long as the company is attempting to correct all factual inaccuracies in the material at issue)
- Choice and/or direct payment of the authors by the pharmaceutical company
- Influence from the pharmaceutical company on the list of persons to whom the material is sent
- Receipt by the pharmaceutical company of a benefit in return for the funding, for example, detailed reports from the organisation. (Note: There is a difference between undertaking due diligence to ensure that funds are used for the intended purpose versus requiring detailed reports which contain analytical data such as traffic to the website.)

The Panel accepted that AstraZeneca had not initiated the symposium, nor influenced the content, speaker selection or attendees. The Panel further acknowledged that the draft agenda did not suggest the symposium would mainly focus on AstraZeneca's medicine or positively position it.

The Panel considered, however, that AstraZeneca would have reasonably foreseen from the draft agenda that its product, eplontersen, would be discussed in the 10-minute slot. The grant proposal, as outlined above, referred to "*emerging classes of drugs"* and highlighted silencers being "*closest to being approved, owing to their proven effectiveness in ATTR-PN".* The Panel noted the symposium recording (at 5:55) included a slide titled *"Silencers for Mixed Phenotype"* and outlined results for eplontersen as well as vutrisiran. AstraZeneca submitted eplontersen was approved in other countries for the treatment of ATTRv-PN and was being evaluated by the European Medicines Agency (EMA) and Medicines & Healthcare products Regulatory Agency (MHRA) for ATTRv-PN at the time of the complaint. It was also in Phase III clinical development for ATTR-CM.

The Panel considered that AstraZeneca received meaningful benefits in return for its funding in the form of detailed reports. This went beyond confirming appropriate use of funds (which would be acceptable due diligence). The Panel concluded, therefore, that the arrangement could not be classed as being at strictly arm's length. On that basis, the Panel determined that AstraZeneca was responsible for the content of the symposium under the Code.

The Panel noted the 17-minute recording extract of the symposium, titled *"Where Are We Now and What's Next in Medical Management?"* covered several emerging therapies in ATTR-CM, including silencers and stabilisers, and was not limited to AstraZeneca's medicine. While the Panel acknowledged the recording did not represent the entire 60-minute symposium, it accepted the complainant's submission that the symposium was promotional material for eplontersen. The recording included the discussion of eplontersen's NEURO-TTransform trial

results for ATTRv-PN and covered the design of the CARDIO-TTransform trial for ATTR-CM, which was described as the largest amyloidosis trial to date.

Clause 3.1

The Panel observed that, at the time of the complaint, eplontersen was being evaluated by the EMA and MHRA for the treatment of ATTRv-PN and was in Phase III clinical development for ATTR-CM. Eplontersen was not licensed for any indication in the UK.

In the Panel's view, the symposium in question promoted AstraZeneca's medicine prior to the grant of its marketing authorisation and, in funding the project in a manner that was not arm's length, AstraZeneca was consequently responsible for the promotion of an unlicensed medicine. The Panel therefore ruled a **breach of Clause 3.1**.

Clause 5.5

Clause 5.5 of the Code required:

> "*Material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which is sponsored by a pharmaceutical company or in which a pharmaceutical company has any other involvement, must clearly indicate the role of that pharmaceutical company.*"

The Panel considered the allegation that *"AstraZeneca tried to distance themselves from their own symposia by running it via a third party, so you had to look carefully to realise they were behind"*. The Panel was unclear whether this referred to the arm's length nature of the arrangement or that AstraZeneca's involvement with the symposium was not clear as it was run by the medical media company. The Panel ruled on the basis of the latter.

The Panel was provided with a copy of the grant agreement, which stated:

> "*Institution* [the medical media company*] agrees to acknowledge AstraZeneca's sponsorship by including an appropriate statement of Support such as: "AstraZeneca has provided a sponsorship grant towards this independent Programme" on written and published materials pertaining to the Programme*."

The Panel also took account of the online programme on the congress's website, which provided that the symposium was "*supported by an unrestricted educational grant from AstraZeneca*." AstraZeneca further submitted it was made clear at the start of the symposium that the session was supported by AstraZeneca *"but they didn't have any impact or influence on content or choosing speakers."*

While the Panel considered it was apparent from the outset that AstraZeneca had provided funding, the terminology used did not clearly describe the nature of its role. The Panel had already determined that the arrangement could not be considered arm's length and queried the use of "*unrestricted*", noting the benefits received in exchange for the funding. The Panel concluded that the declarations used on the materials relating to the programme, on balance, did not clearly indicate AstraZeneca's involvement as required by Clause 5.5. On that basis, the Panel ruled a **breach of Clause 5.5**.

Clause 5.1 and Clause 2

The Panel noted with concern that AstraZeneca had classed the arrangement as an unrestricted grant and considered it to be at arm's length, which was not so. The Panel noted its determination that AstraZeneca was responsible for the content of the symposium, which included promotion of an unlicensed medicine. The Panel considered high standards had not been maintained and ruled a **breach of Clause 5.1**.

Clause 2 was a sign of particular censure and reserved for such use. The supplementary information to Clause 2 included promotion prior to the grant of a marketing authorisation as an example of an activity likely to be in breach of that clause. In this case, eplontersen had not yet been granted a licence in the UK at the time of the symposium but was under review by the regulator.

The Panel noted AstraZeneca's responsibility for the content of the symposium, which led to the promotion of eplontersen prior to the grant of its UK marketing authorisation. However, the Panel took account of the broader context including that the symposium covered a range of other topics and medicines; AstraZeneca submitted that it had not initiated the symposium nor influenced it in any manner. In the Panel's view, the discussion of AstraZeneca's medicine formed a small part of the funded symposium and did not, on balance, amount to activity that brought discredit upon, or reduced confidence in, the pharmaceutical industry. The Panel ruled **no breach of Clause 2**.

Complaint received **13 September 2024**

Case completed **13 October 2025**