

**CASE/0661/07/25**

## **COMPLAINANT v KALVISTA**

### **Alleged promotion of an unlicensed medicine**

#### **CASE SUMMARY**

This case was in relation to a symposium on hereditary angioedema (HAE) at a conference in the UK. The symposium was delivered to health professionals by a third party who had received an educational grant from KalVista. The complainant's allegation was that a KalVista medicine had been promoted during the symposium even though it was not licensed in the UK for treating HAE attacks.

The outcome under the 2024 Code was:

<b>Breach of Clause 3.1</b>	<b>Promoting a medicine prior to the grant of its marketing authorisation</b>
<b>Breach of Clause 5.1</b>	<b>Failing to maintain high standards</b>
<b>No Breach of Clause 2</b>	<b>Requirement that activities or materials must not bring discredit upon, or reduce confidence in the pharmaceutical industry</b>

**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 KalVista Pharmaceuticals Ltd was received from an anonymous, non-contactable complainant who described themselves as a health professional.

#### **COMPLAINT**

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

"Dear Sir/Madam

I am a healthcare professional and I wish to remain anonymous.

I recently attended the [named] conference in [the UK] 13<sup>th</sup>-16<sup>th</sup> June 2025. I attended a session on HAE on Friday 13<sup>th</sup> June, 'Hereditary Angioedema Headlines'. The session was on HAE and sponsored by KalVista Pharmaceuticals, it included a presentation on sebetralstat for the treatment of HAE attacks. It is my understanding that sebetralstat is manufactured by KalVista Pharmaceutical and currently not licensed in the UK for the treatment of HAE attacks.

I wish to make a complaint and ask the PMCPA to investigate this matter and ensure that unlicensed medicinal products are not promoted to healthcare professional under any circumstance.

I enclose the documents associated with the presentation.”

When writing to KalVista, the PMCPA asked it to consider the requirements of Clauses 3.1, 5.1 and 2 of the 2024 Code.

## **KALVISTA’S RESPONSE**

The response from KalVista is reproduced below:

“Thank you for the correspondence dated 16th July 2025 regarding a complaint received under Case/0661/07/25.

KalVista Pharmaceuticals take this matter very seriously and appreciate the opportunity to clarify our position, which is that we do not believe we are responsible for the alleged promotion of sebetralstat as an unlicensed medicine.

The complaint is following an independent medical educational session held by [named third party] at the [named] conference in [named city] on 13th-16th June 2025.

The [named] conference is the annual flagship meeting of the [named academy for health professionals]. KalVista activities, which were un-related to the [named third party] activity, included scientific publications (3 posters, 1 oral presentation, 2 flash talks), company-sponsored HAE disease state symposium, medical affairs booth with disease state education material.

[Named third party] is an independent organisation that provides Continuing Professional Development (CPD). KalVista provided independent medical Educational Grant Support to [named third party] for this session held for Healthcare Professionals (HCPs). This was not a company-sponsored symposium session.

The goal of this independent medical educational activity was for HCPs to be better able to understand the importance of early intervention with on-demand therapies and the role of emerging therapies in simplifying treatment for patients living with hereditary angioedema (HAE). As despite the availability of comprehensive on-demand treatment guidelines, compliance to guideline recommendations remains suboptimal, resulting in persisting unmet need.

[Named third party] developed the content with experts, independent of KalVista, as detailed in Clause 4 of the Education Grant Agreement between KalVista and [named third party].

**Clause 4 from KalVista’s Education Grant Agreement with [named third party]**  
**4. Control of Content and Selection of Presenters.** *Company shall be solely responsible for control of the content of the Activity and the selection of the topic(s) and faculty. Supporter agrees not to direct or influence the content of the Activity or*

*to engage in scripting, targeting points of emphasis or other activities designed to influence the Activity's content.*

**Company:** [named third party] **Supporter:** KalVista.

To also highlight that Clause 3 of the KalVista's Education Grant Agreement with [named third party] details the statement of purpose is not for the purpose of promoting any product:

**Clause 3 from KalVista's Education Grant Agreement with [named third party]**  
**3. Statement of Purpose.** *Company and Supporter agree that the Activity is for scientific and educational purposes and not for the purpose of promoting any product. Any discussion of Supporter's products shall be objective, balanced and scientifically rigorous.*

**Company:** [named third party] **Supporter:** KalVista.

To confirm KalVista has complied with the terms outlined in the Education Grant Agreement.

As requested, the following information is included with this response:

- **Attachment 1:** An original colour copy of the symposium presentation presented by [named third party]. The content included a Live [named third party] Report entitled "Hereditary Angioedema Headlines: Early Intervention Strategies for Managing Attacks and Improving Patient Outcomes" (the "Activity") and included livestreaming, a Social Media Simulcast, a Master PDF Postcard, a Podcast and an Enduring Video Activity. The Live Symposium and Enduring Video Activity each included nursing CPD certification.
- **Attachment 2:** Programme as provided by the complainant. KalVista Pharmaceuticals is mentioned in the Disclosures slide, however in line with Clause 4 of the [named third party] Educational Grant Agreement, [named third party] is solely responsible for the control and content of activity.
- **Attachment 3:** [Symposium] Invitation. The goal of this educational activity was for HCPs to be better able to understand the importance of early intervention with on-demand therapies and the role of emerging therapies in simplifying treatment for patients living with hereditary angioedema (HAE).
- **Attachment 4:** Ekterly (sebetralstat) 300 mg film-coated tablets Summary of Product Characteristics (SmPC). Please note the UK Product Licence (PL 46326/0001) for Ekterly (sebetralstat) 300 mg film-coated tablets was granted by the MHRA, on 15th July 2025.
- **Attachment 5:** CPD Approval Documents. [Named third party] provided the following statement as an official approval that the program is accredited to provide CPD.

#### STATEMENT

The [named faculty of medicine] has reviewed and approved the content of this educational activity and allocated it 1.0 continuing professional development credits (CPD).

- **Attachment 6:** Education Grant Agreement between KalVista and [named third party]. As previously stated, KalVista did not review/approve any materials for the program. The only document KalVista approved is the medical Education Grant Agreement.

Please contact us if you have any questions or require further information.”

## PANEL RULING

This case was in relation to a symposium on hereditary angioedema (HAE) at a UK conference in June 2025. The symposium was delivered to health professionals by a third party who had received an educational grant from KalVista. The complainant’s allegation was that KalVista’s medicine, Ekterly (sebetralstat), had been promoted during the symposium even though it was not licensed in the UK for treating HAE attacks.

The Panel considered that the first question for it to deal with was whether the agreement between KalVista and the third party was an arm’s length arrangement and therefore whether KalVista was responsible for the content of the symposium.

### Was this an arm’s length arrangement?

KalVista provided the Educational Grant Agreement (the Agreement) as part of its response to this complaint. That main body of the Agreement included the following:

1. The title of the symposium was “*Hereditary Angioedema Headlines: Early Intervention Strategies for Managing Attacks and Improving Patient Outcomes*”.
2. The content would be “*developed and distributed*” by the third party.
3. The third party “*shall be solely responsible for control of the content of the [symposium] and the selection of the topic(s) and faculty. [KalVista] agrees not to direct or influence the content of the [symposium] or to engage in scripting, targeting points of emphasis or other activities designed to influence the [symposium]’s content.*”
4. The third party “*will take reasonable steps to ensure that data is objectively selected, evidence-based and presented as a balanced discussion of prevailing scientific information on products and/or alternative treatments.*”

The Agreement had an Annex attached to it, which included a 20-page presentation that the third party presented to KalVista on 18 December 2024. The Panel interpreted this as the third party ‘pitching’ the idea for the symposium to KalVista. This presentation included a large amount of detail about what the symposium would cover, including how it would be broken into segments. It stated that Segment 4 would be about:

*“Breaking News: Innovation in HAE On-Demand Therapies Panellists will review key data and place emerging therapies into clinical context Review on-demand landscape—key data Insights into new delivery methods aimed at simplifying the treatment burden for patients”*

The Panel considered that it is possible under the Code for a company to fund material produced by a third party which mentions that company's products. However, to avoid being liable under the Code for the content of such material, the company must, amongst other things, have a strictly arm's length arrangement with the third party that produces the material. The Panel referred to the Q&A on the PMCPA website titled "*What are arm's length arrangements?*".

That Q&A stated that one of the factors that might mean there has not been an arm's length arrangement is the influence that a company may have over the material. The Panel acknowledged that the main body of the Agreement was reasonably robust in setting out that the third party was responsible for the content of the symposium and that KalVista should not seek to influence it.

However, the PMCPA Q&A also stated that if a company is aware, prior to funding, that the material would mainly discuss the company's medicine and/or positively position it above other treatments then the arrangement might not be considered strictly arm's length.

Given the level of detail the third party provided to KalVista when they met on 18 December 2024, (including that one of the segments was going to "*place emerging therapies into clinical context*"), the Panel considered it very likely that, before agreeing to provide the funding for the symposium on 28 February 2025, KalVista would have known that the symposium would likely mention its product.

The Panel also noted sebetralstat was granted a licence for use in the UK on 15 July 2025 and, at the time of deciding to fund the symposium, KalVista would have likely known that the licencing of its product was expected shortly after the date of the symposium on 13 June 2025. The Panel concluded that the Agreement could not be considered arm's length, and therefore KalVista was responsible under the Code for the content of the symposium. To permit companies to have no responsibility in such circumstances, might allow them to circumvent the requirements of the Code.

### Pre-licence promotion – Clause 3.1

As the requirements for the Agreement to remain arm's length had not been fulfilled, KalVista was responsible under the Code for the content of the symposium. The Panel then reviewed the content of the symposium slides that KalVista had provided.

Of the approximately 40 slides in the presentation, five of them referred to sebetralstat. The slides appeared in a section titled "*Breaking news – Innovation in HAE ON-demand Therapies*", which was referred to as "*Segment 4*" in the presentation the third party delivered to KalVista on 18 December 2024. In particular, the Panel took account of the following two slides, in the context of the broad definition of promotion in Clause 1.17 of the Code:

- slide 25, which was the beginning of the section and titled "*Breaking News - Innovation in HAE On-Demand Therapies*". The Panel viewed this as slightly sensationalist and designed to promote the sebetralstat slides that followed as an exciting new development.
- slide 29, which showed a graph of sebetralstat versus placebo and was headed "*Complete Resolution of HAE Attack*". The Panel considered this to be a claim that was promotional in nature.

The Panel therefore concluded that the slides promoted a pre-licence medicine and ruled a **breach of Clause 3.1**.

Failing to maintain high standards – Clause 5.1

In addition, the Panel considered that KalVista should have taken steps to ensure that the third party was aware of the Code requirements and the prohibition on pre-licence promotion. The Panel acknowledged that the Agreement was prepared in the US and was subject to the laws of the state of New York. However, given that the symposium it related to took place in the UK, the Panel would have expected the Agreement, or other documentation between KalVista and the third party, to have provided for the requirements of the ABPI Code and UK law. In the UK, the prohibition on pre-licence promotion is a legal, as well as a Code, requirement. For these reasons, the Panel concluded that KalVista had failed to maintain high standards and the Panel ruled a **breach of Clause 5.1**.

Discrediting the industry – Clause 2

The Panel took account of the supplementary information to Clause 2, which refers to “*promotion prior to the grant of a marketing authorisation*” as an example of the type of activity that is likely to lead to a breach of Clause 2. However, the Panel considered Clause 2 to be a sign of particular censure and should be reserved for the most serious cases. Given the (albeit unsuccessful) attempt that KalVista had made in the Agreement to seek to make this arrangement arm’s length, the fact KalVista had not contributed to the slides presented at the symposium, and the Panel’s overall impression of those slides, the Panel did not consider that the threshold for a Clause 2 breach had been met in this case. The Panel ruled **no breach of Clause 2**.

**Complaint received**      **15 July 2025**

**Case completed**        **27 January 2026**