

COMPLAINANT v LUNDBECK

Alleged promotion of Vypeti (eptinezumab) at a Lundbeck-funded event

An anonymous, contactable complainant complained about the promotion of Vypeti (eptinezumab) at an event entitled 'Migraine Preceptorship' which was organised and funded by Lundbeck Limited.

COMPLAINT

The complainant stated that the event took place on 24 and 25 November 2020 and had many different participants including an expert patient, a patient organisation representative and several health professionals (ranging from a consultant neurologist to a specialist nurse). Lundbeck UK representatives were also present at this meeting. Lundbeck had a pipeline product for migraine called 'Vypeti (Eptinezumab)' which was a calcitonin gene-related peptide (CGRP) class of product. The session on 24 November 2020 had the following wording on the agenda for the close of day one '(UK-VYEP-0001 Date of Preparation: October 2020) – The future of migraine treatments; how do clinicians, patients and patient organisations view new treatments (and CGRPs), is this exciting and innovative? What impact will they have?'. This session involved discussion amongst all the attendees at the meeting on yet to be licensed eptinezumab (Vypeti). The complainant alleged that this was promotion of a product prior to licence to health professionals and it was also inappropriate to discuss this product or even the class of treatments considering Lundbeck had a particular product in the pipeline within the same class. The complainant stated that with the presence of a patient organisation representative and an expert patient, this topic should have not been discussed; use of the wording 'exciting' and 'innovative' during the discussion and pre-agreed agenda was inappropriate and was to increase interest from attendees. On day two of the meeting, there were further panel Q&A discussions which, again, discussed and mentioned migraine treatments including CGRPs (calcitonin gene-related peptides). The complainant alleged breaches of Clauses 3.1, 9.1 and 2. The complainant stated health professionals gave various presentations throughout the two days and participated in discussions and had been paid far above the normal market rate for their participation at the event considering they were being promoted to about pipeline. The complainant alleged breaches of Clauses 23.1, 9.1 and 2. The complainant further stated that Lundbeck also claimed on the declaration invitations that whilst Lundbeck had selected key topics for discussion, content had been ultimately determined by the named academy. This could not have been accurate as Lundbeck discussed a pipeline product of its own. This was a breach of declaration and the complainant alleged a breach of Clause 9.10.

When writing to Lundbeck, the Authority asked it to consider the requirements of Clauses 2, 3.1, 9.1, 9.10 and 23.1 of the Code as cited by the complainant. Lundbeck was also asked to bear in mind the requirements of Clause 18.1 in relation to the payments to presenters and Clauses 7.2 and 7.10 in relation to the allegation regarding the description 'exciting and innovative'.

RESPONSE

Lundbeck submitted that it took any complaint against the company very seriously and despite the inaccurate nature of this complaint, it had still acted to provide the PMCPA with a thorough and comprehensive response.

Lundbeck submitted that in order to address this complaint in a clear and concise manner it had responded to it in three parts:

- A Background to the event.
- B The complaint in relation to the event and the event content and the alleged breaches cited in this regard (Clauses 2, 3.1, 7.2, 7.10, 9.1 and 9.10).
- C The complaint in relation to the payment of the presenters/trainers above the normal market rate and that payment was connected to the promotion of a medicine and the alleged breaches cited in this regard (Clauses 2, 9.1, 18.1 and 23.1).

A Background to the event

Lundbeck submitted that this event was a Migraine Preceptorship initiated, organised and funded by Lundbeck UK to provide internal training in order to increase the understanding and knowledge of the migraine therapy area amongst Lundbeck UK and Business Area North (Europe) internal medical and market access staff. There were no sales representatives at the training (a copy of the full list of attendees and their roles within Lundbeck was provided).

The named academy was an education provider who had a strong heritage in the delivery of bespoke education programmes for pharmaceutical companies. The academy's training was provided by an academic faculty of clinicians and experts focusing on neurological conditions and disease management.

Lundbeck explained that it approached the named academy to support the development and service delivery of the Migraine Preceptorship Programme and subsequently contracted them as a training service provider. The academy subsequently designed a programme of training content to address the four key topics set out by Lundbeck to provide a comprehensive Migraine Preceptorship Programme for Lundbeck's employees only. The academy subsequently used its faculty of clinicians and experts to provide the training.

Lundbeck provided the academy with a list of the internal attendees to be invited by the to register for the event, once these attendees registered, their details were manually reviewed and verified before they received any login details and were able to access the event and all the associated materials (the registration invitation email, the subsequent notification of the verification process email and the email confirmation that the account had been approved and that the event could now be accessed was provided). Lundbeck submitted that, therefore, access to this event and the associated materials was restricted to the internal attendee list provided by Lundbeck and was cross-checked by the academy which verified that only these attendees were able to join (data analytics breakdown showing everyone who accessed the event was provided).

The wording 'is this exciting and innovative?' cited by the complainant with regard to new treatments related to the title and description of a specific training session on the internal agenda for the event. The clear and prominent disclaimer '**FOR INTERNAL USE ONLY**' on the

same agenda made it clear that this was an internal event, whereas the additional disclaimer above this clearly highlighted that Lundbeck had sponsored/funded the event (the full agenda of the two-day internal training event was provided).

B Complaint (in relation to the event and its content) and alleged breaches

Lundbeck submitted that this event, as comprehensively outlined above and evidenced (through the enclosures provided), was an internal Lundbeck training event for Lundbeck Head Office employees to increase their knowledge of the migraine therapy area and the associated treatments. This was not a promotional activity and the clinicians in attendance were from the training service providers faculty of experts who Lundbeck had contracted with to provide this bespoke education programme. Similarly, the wording used on the agenda was to describe the different training sessions being held across the two-day training event funded by Lundbeck, the agenda was an internal document for internal Lundbeck attendees and had prominent disclaimers to this effect. Therefore, it was not promotional material and subsequently the wording used would not constitute a claim.

As a result, Lundbeck refuted any breach of Clauses 3.1, 7.2, 7.10 and 9.10 as there was no promotion associated with this event and Lundbeck had clearly indicated that it had funded this internal training.

Subsequently, Lundbeck also refuted any breach of Clauses 2 and 9.1 as this was a legitimate internal training event run to a high standard to ensure that appropriate Lundbeck Head Office staff had a thorough understanding and knowledge of the migraine therapy area.

C Complaint (in relation to the payment of the presenters/trainers above the normal market rate and that payment was connected to the promotion of a medicine) and alleged breaches

Lundbeck submitted that the payment of the clinicians was for the training provided and was reasonable and in line with Lundbeck's rate card and reflected fair market value as evidenced (copies of the breakdown of each speaker's payment and the Lundbeck rate card was provided). Subsequently, it was not connected in any way with the promotion of medicines as alleged, therefore Lundbeck refuted any breach of Clauses 18.1 and 23.1.

As a result, Lundbeck also refuted any breach of Clauses 2 and 9.1 as payment was for the provision of internal training and therefore not connected with promotion, additionally payments were reasonable and reflected fair market value as evidenced. Therefore, high standards were maintained.

Summary

Lundbeck UK considered healthcare compliance of the utmost importance and it was continuing its journey of implementing new and improved measures to ensure that company employees always had compliance at the forefront of their thoughts when executing activities and producing company materials.

Lundbeck submitted that it was, therefore, dismayed that it had received this complaint, a very frustrating development when, as was the case here, the complainant provided no evidence and subsequently no *prima facie* case to answer with regard any of the clauses alleged. Lundbeck

felt this was a clear attempt to continue to distract it from its ongoing plans and compliance progress as a conscientious and responsible company.

Lundbeck therefore asked, on receipt of this response, that the Case Preparation Manager, in line with Section 5.5 of the PMCPA Constitution and Procedure, made the determination that there was no *prima facie* case established here and advised that, as such, Lundbeck had no case to answer at their earliest convenience.

PANEL RULING

The Panel noted that the Constitution and Procedure stated that the complainant had the burden of proving his/her complaint on the balance of probabilities. All complaints were judged on the evidence provided by the parties.

The Panel noted Lundbeck's submission that the Migraine Preceptorship Programme, held on 24 and 25 November 2020, was organised by Lundbeck to provide internal training for relevant Lundbeck head office staff and no sales representatives were present. The Panel noted Lundbeck's submission that it had contracted the named academy to design a programme of training content to address four key topics set out by Lundbeck to increase Lundbeck head office employees' knowledge of the migraine therapy area and associated treatments. The four key topics were: to gain an in-depth understanding of the management of migraine within the UK market and current treatment options from specialist clinicians; to understand the role of differing clinicians in the development and delivery of services; to have an overview of current policy on service development; and to gain a better understanding of the impact of migraine from a patient perspective and how patient organisations both support patients and influence policy.

Clause 9.10 stated that material relating to medicines and their uses, whether promotional or not, and information relating to human health or diseases which was sponsored by a pharmaceutical company must clearly indicate that it had been sponsored by that company.

The Panel noted the complainant's allegation that the declaration of sponsorship on the invitation could not have been accurate as Lundbeck discussed a pipeline product of its own. The declaration read 'This activity had been funded by Lundbeck. Whilst Lundbeck has selected key topics for discussion, content has been ultimately determined by [named academy]'. Noting Lundbeck's explanation, the Panel did not consider that the complainant had established that the declaration in question was inaccurate as alleged, and no breach of Clause 9.10 was ruled.

The Panel noted there was a clear difference between attending a meeting as a speaker and attending as a delegate. The Panel further noted Lundbeck's submission that none of the health professionals at the meeting were delegates; they had been contracted to deliver internal company training. The Panel noted that Lundbeck did not specifically comment on the complainant's concern about the presence of a patient organisation representative and an expert patient. The Panel noted, however, that an expert patient and member of the patient organisation, were also listed on the preceptorship invitation as speakers and thus also appeared not to have attended the meeting as delegates. The expert patient delivered a session titled 'A personal perspective of living with migraine' which included experience of the NHS and impact on life and work. The patient organisation representative delivered a session

titled 'The role of patient organisations in the management of migraine' which included patient perspective, influencing service provision and providing services closer to home, and education.

The Panel noted that the complainant bore the burden of proof and had provided no details about the presence and role of the speakers throughout the meeting. That individuals had been present at meetings as speakers under *bona fide* arrangements was insufficient, in the absence of additional evidence, to establish that they were thereby the subject of promotional activity. The Panel thus did not consider that there was evidence that eptinezumab had been promoted to any health professional, patient or patient organisation representative prior to the grant of its marketing authorisation as alleged and no breach of Clause 3.1 was ruled. The Panel consequently ruled no breach of Clauses 9.1 and 2.

The Panel noted Lundbeck's submission that the clinicians in attendance were from the training service provider's faculty of experts and the payment of the clinicians for the training provided was reasonable and in line with Lundbeck's rate card and reflected fair market value.

The Panel noted that the complainant bore the burden of proof and did not consider that he/she had established that the payments made to the healthcare academy faculty speakers were inappropriate as alleged. The Panel therefore ruled no breach of Clause 23.1 and consequently ruled no breach of Clauses 9.1 and 2.

The Panel did not consider that there was any evidence that payments to the healthcare academy faculty constituted an inducement to prescribe, supply, administer, recommend, buy or sell any medicine and no breach of Clause 18.1 was ruled.

In relation to use of the words 'exciting' and 'innovative', the Panel disagreed with the principle of Lundbeck's submission that there had been no breach of Clauses 7.2 and 7.10 as there was no promotion associated with the event and that as it was not promotional material and subsequently the wording used would not constitute a claim. The Panel noted that whilst Clause 7.10 referred to promotion, Clause 7.2 applied to all information, claims and comparisons and was not limited to promotion.

The Panel noted the complainant's concern that use of the words 'exciting' and 'innovative' during the discussion and pre-agreed agenda was inappropriate and was used to increase interest from attendees. The Panel noted that the agenda on 24 November 2020 stated below the title 'Panel discussion Q&A session', 'The future of migraine treatments; how do clinicians, patients and patient organisations view new treatments (and CGRPs), is this exciting and innovative? What impact will they have?'. The Panel noted that the agenda included 'FOR INTERNAL USE ONLY' in bold black font at the bottom of the invitation and the complainant's concern appeared to be in relation to external attendees. The Panel noted that there was no evidence to support the complainant's allegation that the words 'exciting' and 'innovative' were the subject of discussion. The Panel further noted its comments above about the status of the external attendees as speakers, as opposed to delegates, and based on the very narrow allegation, ruled no breach of Clauses 7.2 and 7.10.

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During its consideration of this case, the Panel noted that MSLs who would likely be asked by health professionals for information about the company's unlicensed medicines had attended the preceptorship and it queried the appropriateness of the use of the terms innovative and

exciting when referring to the company's yet to be licensed medicine in this regard. The Panel requested that Lundbeck be advised of its concerns.

Complaint received **27 April 2021**

Case completed **1 April 2022**