GENERAL PRACTITIONER v BOEHRINGER INGELHEIM & LILLY

Alleged promotion of Trajenta

A general practitioner alleged that an educational meeting jointly sponsored by Boehringer Ingelheim and Eli Lilly & Company to discuss referrals to the renal clinic and the management of kidney health and care, was the disguised promotion of Trajenta (linagliptin). The two companies co-promoted Trajenta (linagliptin) for the treatment of type 2 diabetes.

The complainant submitted that when referring to the management of diabetic complications the speaker made unfettered reference to the key marketing messages for Trajenta, ie no modification of dosage necessary in diabetics with renal disease, that Trajenta represented an unmet need in such patients compared with other medicines in the same class, the inference that other medicines in the class were suboptimal and represented an unacceptable safety profile and that Trajenta improved compliance by virtue of its single dosage strength. No counterpoints were offered in favour of the other medicines in the class.

The detailed response from the two companies is given below.

The Panel noted Boehringer Ingelheim and Lilly's submission that the meeting was organised at the behest of a GP partner who requested an educational meeting to discuss the referral of patients with renal impairment from primary to secondary care. A Lilly representative co-ordinated the meeting and the speaker (suggested by the GP partner) had agreed to be the sole speaker. A Boehringer Ingelheim representative had attended.

The speaker had created his own slide deck and the Panel noted from the speaker/consultant agreement submitted by the companies that the title of the meeting was 'When to refer to the Renal Clinic'. The speaker brief stated that the objective of the presentation was to discuss appropriate referral to the renal clinic, renal disease, complications and the management of patient care.

The Panel noted that the invitation described the meeting as an educational meeting for all health professionals where the speaker would discuss referrals to the renal clinic and management of kidney health and care.

The Panel noted that the Lilly speaker briefing referred to the presentation and the requirements of the Code. The briefing advised that it was the speaker's responsibility to ensure that the information in the slides was, *inter alia*, capable of substantiation and, in relation to non-Lilly products, fair, balanced, non-disparaging and consistent with the product label.

The Panel noted that the presentation entitled 'Referral: who, how, and if not, why not?', did not mention any specific medicine. A slide referring to quality outcome framework indicators referred to the percentage of patients with chronic kidney disease treated with an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB). From the slides it appeared that the presentation was about chronic kidney disease in general rather than that associated with diabetes and was consistent with the invitation in that regard.

The Panel noted that an email from the speaker submitted by Boehringer Ingelheim and Lilly stated *inter alia*, that his discussion of individual medicines or the management of diabetic renal disease. The speaker stated that on review of the slides none were promotional and no slides referred to diabetic renal disease or its management.

The Panel noted that the representative who was at the meeting had stated that questions were raised during the presentation on referrals to hospital but none were raised about Trajenta, either during or after the presentation, to the representative or the speaker.

The Panel noted that the parties' accounts differed. A decision had to be made on the evidence before it. A complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted Boehringer Ingelheim and Lilly's submission and the accounts provided by the speaker and representative that there was no reference to Trajenta at the meeting. The complainant did not respond to a request to comment on the companies' response.

The Panel considered that the complainant had failed to establish that Trajenta was discussed at the meeting and consequently that any such discussion, including comparisons with other medicines within its class, was misleading and unbalanced as alleged. There was no evidence that any medicine had been disparaged as alleged. There was no evidence before the Panel to indicate that the meeting had promoted Trajenta and thus it was not disguised in that regard. No breaches of the Code were ruled.

A general practitioner complained about a local educational meeting jointly sponsored by Boehringer Ingelheim Limited and Eli Lilly & Company Limited to discuss referrals to the renal clinic and the management of kidney health and care. The meeting 'When to refer to the renal clinic' was held in April 2012. Boehringer Ingelheim and Lilly co-promoted Trajenta (linagliptin) for the treatment of type 2 diabetes.

COMPLAINT

The complainant stated that in his/her view the presentation, and in particular the speaker's comments on the management of diabetic complications, was overwhelmed by the unbalanced discussion and disguised promotion of Trajenta. For example, the speaker made unfettered reference to the key marketing messages for Trajenta, ie no modification of dosage necessary in diabetics with renal disease, that Trajenta represented an unmet need in such patients compared with other medicines in the same class, the inference that the other medicines in the class were suboptimal and represented an unacceptable safety profile and that Trajenta improved compliance by virtue of its single dosage strength. No counterpoints were offered in favour of the other medicines in the class.

When writing to Boehringer Ingelheim and Lilly the Authority asked the companies to respond in relation to the requirements of Clauses 7.2, 7.3, 8.1 and 12.1.

RESPONSE

Boehringer Ingelheim and Lilly had co-sponsored the non-promotional, educational meeting in question. The meeting was organised at the behest of a GP partner at the local health centre who had asked for an educational meeting to discuss the referral of patients with renal impairment from primary to secondary care.

The meeting was coordinated by a Lilly representative. The speaker, suggested by the GP, was considered an expert on this topic. The speaker agreed to be the sole speaker at the meeting. The Lilly representative made arrangements with the speaker that the meeting would be a non-promotional/educational event. The speaker created his own slide deck to discuss appropriate referrals to the renal clinic, renal diseases, complications and the management of patient care.

Lilly did not agree to the speaker's initial request to do the talk independently without paperwork and internal compliance procedures were duly followed and the meeting was documented. The speaker was briefed by the Lilly representative and the Lilly compliance administration team using a speaker briefing document (a copy was provided). No other materials were provided and the speaker prepared his own slides, which Lilly reviewed before the meeting. As per the speaker agreement, the slide review focused on fairness, balance, non-disparaging content, safety and consistency with the product label. As this was an educational meeting the review ensured that the slides contained no promotional content.

All meeting arrangements were finalised in accordance with Lilly standard operating procedures and the Code. The meeting invitation was approved and expressly referred to its educational nature, leaving the invitee in no doubt they would be attending an educational, non-promotional meeting. No promotional material was used or distributed during the meeting and as it was a non-promotional meeting no stand or promotional activity was permitted. The meeting was well attended.

Due to unforeseen circumstances the Lilly representative was unable to attend but arranged for a Boehringer Ingelheim representative to be there to ensure that the meeting ran smoothly. No other representative attended the meeting or was involved in any way.

The speaker's presentation, 'Referral: who, how, and if not, why not?' covered the meeting objectives referred to above and did not mention any treatment or products used in the management of type 2 diabetes including Trajenta. The Boehringer Ingelheim representative strongly refuted any suggestion that further discussion took place on any products including Trajenta. As no product discussions took place there was no scope for product comparisons. The companies noted that two attendees raised questions on the exact process of referring their patients to secondary care renal clinics, which further demonstrated the educational nature of the discussions at the meeting.

Based on the slide content, feedback from attendees and overall meeting arrangements, the companies were confident that this educational meeting was not in breach of Clauses 7.2, 7.3, 8.1, or 12.1.

In conclusion, Boehringer Ingelheim and Lilly noted the feedback from one of the attendees who stated that 'It's appreciated that Lilly will ask a consultant to speak covering our educational needs rather than a "promotional" talk'.

The companies submitted that the evidence outlined above demonstrated that they had complied with all requirements of the Code in terms of this educational meeting and therefore disputed the allegation that it constituted disguised promotion of Trajenta.

Following a request for further information, Boehringer Ingelheim and Lilly stated that they were fully committed to ensuring that all their activities were fully compliant with the Code and were disappointed that the complaint had been raised.

In relation to the phrase 'further discussions' at the meeting in question, the companies submitted that the meeting was entirely education and service related. There was no scope for product discussion at any point before, during, or after the meeting. The phrase, 'further discussions' was to emphasise clearly the educational purpose of this event. This was further evidenced by the statements from both the speaker and the Boerhinger Ingelheim representative, who were both clear in their recollection of the meeting as being fully non-promotional.

PANEL RULING

The Panel noted Boehringer Ingelheim and Lilly's submission that the meeting in question was organised at the behest of a GP partner who requested an educational meeting to discuss the referral of patients with renal impairment from primary to secondary care. The GP partner suggested the speaker as he was considered an expert on this topic. The meeting was coordinated

by a Lilly representative and the speaker had agreed to be the sole speaker at the meeting. A Boehringer Ingelheim representative had attended the meeting.

According to the companies the speaker had created his own slide deck with the objective of discussing appropriate referrals to the renal clinic, renal diseases, complications and the management of patient care. The Panel noted from the speaker/consultant agreement submitted by the companies that the title of the meeting was 'When to refer to the Renal Clinic'. The speaker brief stated that the objective of the presentation was for the speaker to discuss appropriate referral to the renal clinic and that the talk should discuss renal disease, complications and the management of patient care.

The Panel noted that the invitation to the meeting described it as an educational meeting for all health professionals where the speaker would discuss referrals to the renal clinic and management of kidney health and care.

The Panel noted that the Lilly speaker briefing referred to the presentation and the requirements of the Code, including Clauses 7.2 and 7.4. The briefing advised that it was the speaker's responsibility to ensure that the information in the slides was, *inter alia*, capable of substantiation and, in relation to non-Lilly products, fair, balanced, non-disparaging and consistent with the product label. There was no guidance about how the slides should be explained to the audience.

The Panel reviewed the presentation entitled 'Referral: who, how, and if not, why not?'. It provided a background to chronic kidney disease then discussed which patients should be seen in the renal clinic; the role of the renal clinic; reasons for referral; profiles for patients who should and should not be referred and advice on how to refer. There was no mention of any specific medicine. A slide referring to quality outcome framework indicators referred to the percentage of patients with chronic kidney disease treated with an angiotensin converting enzyme inhibitor (ACE-I) or angiotensin receptor blocker (ARB). From the slides it appeared that the presentation was about chronic kidney disease in general rather than that associated with diabetes and was consistent with the invitation in that regard.

The Panel noted that an email from the speaker submitted by Boehringer Ingelheim and Lilly stated that he had no recollection of making any promotional comments during his talk which was very clearly on the referral of patients to the renal clinic. Discussion of individual medicines and the management of diabetic renal disease did not occur. The speaker stated that on review of the slides none were promotional and no slides referred to diabetic renal disease or its management. The speaker further stated that he knew nothing about Trajenta and had no practical or theoretical experience of its use. He had approached a GP in the practice where the meeting had been held who attended the meeting and who agreed that there was no promotional content nor were any promotional slides used. The speaker was disappointed that the complainant's concerns had not been raised directly.

The Panel noted that a statement from the representative who was present at the meeting stated that there were a number of questions raised during the presentation on referrals to hospital but no questions were raised about Trajenta, either during or after the presentation, to the representative or the speaker.

The Panel noted that the parties' accounts differed. A decision had to be made on the evidence before it. As stated in the Constitution and Procedure a complainant had the burden of proving his/her complaint on the balance of probabilities. The Panel noted Boehringer Ingelheim and Lilly's submission and the accounts provided by the speaker and representative that there was no reference to Trajenta at the meeting in question. The complainant was asked to comment on the companies' response to the complaint but did not respond.

The Panel considered that the complainant had failed to establish that Trajenta was discussed at the meeting and consequently that any such discussion, including comparisons with other medicines within its class, was misleading and unbalanced as alleged. No breach of Clauses 7.2 and 7.3 was ruled. There was no evidence that any medicine had been disparaged as alleged and thus no breach of Clause 8.1 was ruled. There was no evidence before the Panel to indicate that the meeting was promoting Trajenta and thus it was not disguised in that regard. No breach of Clause 12.1 was ruled.

Complaint received **25 June 2012**

Cases completed **14 September 2012**