CASES AUTH/2540/11/12 and AUTH/2545/11/12 NO BREACH OF THE CODE

ANONYMOUS v ELI LILLY and BOEHRINGER INGELHEIM

Promotional meeting allegedly disguised as education

A non-contactable clinician complained anonymously about a meeting held jointly by Lilly and Boehringer Ingelheim. The companies jointly marketed Trajenta (linagliptin), a dipeptidyl peptidase 4 (DPP-4) inhibitor for the management of type 2 diabetes and Jentadueto (linagliptin and metformin) also for the management of type 2 diabetes. Lilly also marketed Byetta (exenatide), a glucagon-like peptide-1 (GLP-1) receptor agonist for the management of types 1 and 2 diabetes.

The complainant stated that some years ago he/she had stopped meeting representatives because of their behaviour and the swollen numbers who sold the same medicine.

The complainant stated that Lilly's meeting was advertised as a means of understanding how the new diabetes medicines fitted into patient care. As a lead on diabetes the complainant thought this would be useful and probably in keeping with the meetings other companies had offered locally. However, despite the assurance of genuine medical education, the meeting overtly promoted Trajenta and Byetta. The speakers were little other than paid sales people for Lilly and the questionnaire asked which particular DPP-4 inhibitor the reader currently used and if the meeting had changed that choice. The complainant submitted that this clearly indicated that this was a sales meeting disguised as genuine education. As the meeting ended, the representatives poured into the meeting room and handed out prescribing information. The complainant understood that this was illegal.

The detailed responses from Lilly and Boehringer Ingelheim are given below.

The Panel noted that the complainant was anonymous and non-contactable. Such complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities.

The Panel did not know how the complainant had found out about the meeting. A journal advertisement which promoted the meeting was entitled 'Complexity of type 2 diabetes. A hands-on guide to simplify care in clinical practice'. A prominent highlighted box featured the sponsoring companies' logos and the explanation that 'These meetings have been developed by [the publisher of a diabetes journal] in conjunction with, and sponsored by, Boehringer Ingelheim Ltd and Eli Lilly and Company Limited'. In a separate highlighted box to the right were the logos for the journal and its publisher. Beneath the two boxes, in a prominent white typeface, the reader was told where to find prescribing information for linagliptin. The advertisement gave brief details of the programme committee and a short introduction alongside their photographs stated 'We have designed this series of complimentary meetings …' and 'We look forward to welcoming you …' although it was unclear who 'we' were. The invitation detailed the agenda for the half day meeting which began at 12 noon with lunch and registration. Three presentations, 'All change! What you need to know about diagnosing type 2 diabetes now', 'Understanding the spectrum of different glucose-lowering drugs available', 'Understanding the relationship between diabetes, glucose-lowering drugs and cardiovascular disease' and 'Requirements after prescribing: what to monitor, when and why?' were followed by an 'Ask the experts session'. The meeting concluded at 4:45pm. The other invitation formats were closely similar in content although the layout differed; an email invitation provided a less detailed account of the agenda. All featured the prominent description of the companies' involvement and, all apart from a flyer, had a link to prescribing information. The Panel was concerned that the flyer did not contain prescribing information. All material had to be capable of standing alone in relation to Code

compliance. There was no allegation in relation to the absence of prescribing information. The Panel noted that the prominent highlighted box describing the companies' involvement as 'in conjunction with, and sponsored by' appeared on pages 1, 2 and 4 of the four page flyer. The Panel considered it would have been helpful if more information about the status of the programme committee had been given and in that regard had some sympathy with the complainant. However, overall, the Panel considered that from the description of the companies' involvement, 'in conjunction with, and sponsored by', it was sufficiently clear that they did not have an arm's length arrangement with the publisher and that the companies' involvement went beyond the provision of finance. The average invitee would reasonably expect the agenda to discuss, inter alia, the companies' products and thus be categorized under the Code as promotional in this regard.

The Panel noted that it was also possible that the complainant had been invited by postal invitation or telephone. There was no way of knowing whether this was so and precisely what had transpired. The Panel noted that whilst representatives had delivered invitations, the complainant had stated that he/she had stopped meeting representatives some years ago.

The Panel noted that all meetings had to comply, inter alia, with the Code and have a clear educational content. The Panel noted that each presentation was accompanied by speaker notes.

The Chair's introductory presentation discussed the complexity of the current prescribing environment including cost. The first presentation discussed diagnosis including detailed case scenarios. The second presentation 'Understanding the spectrum of different glucose-lowering drugs available' outlined the advantages and disadvantages and discussed each class of medicine; linagliptin and exenatide were referred to. The presentation concluded with a discussion of published guidance on the management of hyperglycaemia (NICE, QUIPP etc); one of the take-home messages was 'However, the choice of agent depends on the specific circumstances and needs of the person with type 2 diabetes'. The third presentation, which discussed the relationship between diabetes, glucose-lowering drugs and cardiovascular (CV) disease, summarized CV outcomes of the major clinical trials. Cardiovascular outcome data for inter alia, exenatide and linagliptin were discussed. The final presentation discussed renal function monitoring and referred to medicines across all classes in relation to renal impairment. One slide favourably compared the clinical characteristics (dose adjustment, monitoring etc) of linagliptin with other DPP-4 inhibitors.

The Panel noted that speakers were briefed that, in addition to examining the key complexities of type 2 diabetes in clinical practice, the meetings aimed to provide information on the role of linagliptin and specifically in potentially reducing the management complexity of this condition. The Panel considered that such an aim was not necessarily unacceptable so long as the meetings and advertisements about them complied with the Code. The Panel noted its comments above about the impression given by the invitation. The Panel also noted that the detailed speakers' briefing in relation to the individual presentations appeared balanced and only mentioned linagliptin once.

The Panel noted the clear educational content of the meeting as set out above and ruled no breach of the Code. The Panel noted its comments above about the role of the companies, the publisher and the programme committee as set out in the invitations. The requirement in the Code about declarations and meetings related solely to sponsorship and in that regard the Panel considered that the companies' sponsorship had been disclosed on the invitations and on the slides; no breach of the Code was ruled.

It was not necessarily unacceptable for a questionnaire to enquire about a delegate's current and future prescribing decisions so long as it complied with the Code. Delegates did not have to provide the information. The Panel also noted that contrary to the complainant's account, the companies submitted that no representatives had entered the meeting room. It was not possible to determine where the truth lay. Whilst the parties' accounts differed, the Panel noted that it was not necessarily unacceptable for representatives to enter the main meeting room in relation to the meeting at issue.

The Panel noted that it had no way of knowing what was actually said by the speakers at the meeting in question. The Panel considered that the meeting was promotional for the companies' products mentioned. However, bearing in mind the impression given by the invitations as outlined above the Panel did not consider that its promotional nature was disguised as alleged; no breach of the Code was ruled. The Panel also ruled no breach of the Code in relation to maintenance of high standards.

A non-contactable clinician complained anonymously about a meeting held by Eli Lilly and Company Limited. Lilly stated in its response that, together with Boehringer Ingelheim Ltd, it had formed the Diabetes Alliance (the Alliance) and that the meeting in question was a joint meeting with Boehringer Ingelheim. The complaint was thus also taken up with that company (Case AUTH/2545/11/12).

Lilly and Boehringer Ingelheim jointly marketed Trajenta (linagliptin), a dipeptidyl peptidase 4 (DPP-4) inhibitor for the management of type 2 diabetes and Jentadueto (linagliptin and metformin) also for the management of type 2 diabetes. Lilly also marketed Byetta (exenatide), a glucagon-like peptide-1 (GLP-1) receptor agonist for the management of types 1 and 2 diabetes.

COMPLAINT

The complainant stated that some years ago he/she had stopped meeting pharmaceutical industry representatives because of the appalling record they had in terms of their behaviour in the promotion of their products as well as the swollen numbers of representatives who sold the same medicine.

In recent months the complainant had been led to believe that sharp practice was a thing of the past and that the companies were now more supportive of the NHS. Certainly some of them had helped the complainant's primary care trust (PCT) and provided good support for some meetings. The complainant had started to believe the leopard had changed its spots. Sadly this had been proved wrong.

The complainant stated that he/she had attended what was advertised as a genuine medical education event that turned into the bad old days of the pharmaceutical companies. Lilly's meeting, at a local hotel, was advertised as a means of understanding how the new medicines in diabetes fitted into patient care. As the complainant led on diabetes he/she thought this would be useful and probably in keeping with the meetings other companies had offered locally.

The complainant alleged that despite the assurance of genuine medical education, the meeting overtly promoted Trajenta and Byetta. The speakers were little other than paid sales people for Lilly. In fact, the questionnaire distributed asked, for example, which particular DPP-4 inhibitor the reader currently used and if the meeting had changed that choice.

The complainant submitted that this was a clear indication that this was a sales meeting disguised as genuine education. As the meeting came to an end, the representatives poured around the attendees into the meeting room and handed out prescribing information to take away. The complainant understood that this was illegal. The complainant stated that many of his/her colleagues were appalled.

The complainant stated that he/she and his/her colleagues considered that Lilly had set the industry back by years.

When writing to Lilly and Boehringer Ingelheim, the Authority asked the companies to respond in relation to Clauses 9.1, 12.1, 19.1 and 19.3 of the Code.

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RESPONSE

Lilly submitted that the meeting in question was held in the 4 star Hilton Hotel in Blackpool on 7 November 2012. It was one of a series of identical promotional meetings entitled 'Complexity of type 2 diabetes, a hands-on guide to simplifying care in clinical practice', run at various venues throughout the UK. The meetings contained a certain amount of educational content as well as information on Trajenta. All materials relating to these meetings had been certified. The meetings were organised on the Alliance's behalf by a publishing group.

This series of promotional meetings was advertised via a number of channels:

- a meeting page in the events section of the website 'Diabetes on The Net'
- an advertisement in Diabetes in Practice, Diabetes Digest, Diabetes & Primary Care, Journal of

Diabetes Nursing, The Diabetes Foot Journal,

PCDS, Diabetes Care for Children & Young People

- a general email mailing
- a flyer accompanied by a meeting invitation sent by post or separately delivered by a representative during a promotional call.

It was not clear from the complaint which of these channels the complainant had responded to about the meeting. All items fulfilled the requirements for promotional materials including the product name, non-proprietary name, black triangle and prescribing information.

Trajenta and Jentadueto were currently the only licensed and marketed products of the Alliance. Although the meetings were promotional, it was clear from the agenda and the content of the presentations that the meetings were mainly educational, focusing on the overall management of type 2 diabetes. Lilly acknowledged that the meeting was promotional with respect to Trajenta, however, it strongly refuted the complainant's comments about the alleged promotion of Byetta. Whilst all classes of the medicines used to manage type 2 diabetes were discussed as per the agenda, a single mention of exenatide specifically was made on one slide with no use of the brand name; additionally exenatide was also mentioned along with other therapies in four other slides. All presentations in which any products were mentioned also ended by another clear slide informing the audience of the availability of prescribing information for Trajenta, in compliance with the Code.

Attendees were invited to arrive at the meeting from noon onwards. During registration they were advised that a buffet lunch was provided in a separate room, where a Trajenta promotional stand was set up and manned by three sales representatives from both companies. Copies of the materials used and displayed on the stand were provided. These included Trajenta and Jentadueto leavepieces, a quick reference guide to type 2 diabetes and chronic kidney disease and the Trajenta summary of product characteristics (SPC).

At about 12:45pm, delegates were asked to take their seats in a separate meeting room for the start of the presentations at 12:50pm. There was a half hour coffee break at 2:20pm and the

meeting concluded with an 'Ask the experts' question and answer session. All delegates were given an evaluation form with the Trajenta prescribing information attached, a Continuing Professional Development Workbook and a programme book with speaker biographies. The agency staff collected any completed evaluation forms and handed out certificates of attendance. Lilly submitted that the Alliance representatives did not enter the meeting room either during or after the sessions. The representatives' interactions with delegates were limited to the room where the Trajenta stand was set up. Excluding Alliance staff, there were 26 attendees. Therefore, based on this, Lilly refuted the complainant's allegations.

The speakers were a head of a diabetes and endocrinology hospital department, a consultant diabetologist and a diabetes specialist nurse and nurse consultant. They were contracted and paid in accordance to the Alliance's procedures and policies on payments speaker contracts. They were invited and briefed by the agency.

Lilly submitted that all reasonable steps had been taken to ensure not only the transparency around the promotional nature of this meeting but also the high quality of the presentations. However, upon receiving this anonymous complaint, and in order to negate any possible misinterpretations for the remaining meetings of the series, it had contacted each registered attendee for upcoming meetings to remind them that Trajenta information would be discussed at the meeting and reiterated the option for them to unsubscribe from the meeting if they wish.

Based on the actions set out above, Lilly submitted that it had maintained high standards pre-meeting according to the Clause 9.1 and had provided clear information on the meeting in accordance with Clauses 12.1, 19.1 and 19.3 of the Code.

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RESPONSE

Boehringer Ingelheim stated that it was fully aligned with Lilly's response.

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PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. Such complaints were accepted and like all complaints judged on the evidence provided by the parties. The complainant had the burden of proving his/her complaint on the balance of probabilities.

The complainant alleged that despite an assurance of genuine medical education the meeting overtly promoted Trajenta and Byetta. In this regard the complainant referred to the speakers, the questionnaire and commented on the conduct of representatives.

The Panel did not know how the complainant had found out about the meeting and it was not possible to contact the complainant to ascertain this. The journal advertisement which promoted the meeting was entitled 'Complexity of type 2 diabetes. A hands-on guide to simplify care in clinical practice'. A prominent highlighted box featured the sponsoring companies' names in logo format and the explanation that 'These meetings have been developed by [the publisher of a diabetes journal], in conjunction with, and sponsored by, Boehringer Ingelheim Ltd and Eli Lilly and Company Limited'. In a separate highlighted box to the right were the logos for the journal and publisher. Beneath the two boxes, in a prominent white typeface, the reader was told where to find prescribing information for linagliptin. The advertisement gave brief details of the programme committee and alongside their photographs gave a short introduction to the meeting. The introduction stated 'We have designed this series of complimentary meetings …' and 'We look forward to welcoming you …' although it was unclear who 'we' were. The invitation also detailed the agenda for the half-day meeting which began at 12 noon with lunch and registration. The

Chair's address was followed by three presentations: 'All change! What you need to know about diagnosing type 2 diabetes now'; 'Understanding the spectrum of different glucose-lowering drugs available'; 'Understanding the relationship between diabetes, glucose-lowering drugs and cardiovascular disease' and 'Requirements after prescribing: what to monitor, when and why?'. The presentations were followed by an 'Ask the experts session'. The meeting concluded at 4:45pm. The other invitation formats were closely similar in content to the journal advertisement although the layout differed; the email invitation provided a less detailed account of the agenda. All featured the prominent description of the companies' involvement and, all apart from the flyer, had a link to prescribing information. The Panel was concerned that the flyer did not contain prescribing information. All material had to be capable of standing alone in relation to Code compliance. There was no allegation in relation to Clause 4.1 and prescribing information. The Panel noted that the prominent highlighted box describing the companies' involvement as 'in conjunction with, and sponsored by' appeared on pages 1, 2 and 4 of the four page flyer. The Panel considered it would have been helpful if more information about the status of the programme committee had been given and in that regard had some sympathy with the complainant. However, overall, the Panel considered that the description of the companies' involvement as 'in conjunction with, and sponsored by' made it sufficiently clear that the companies did not have an arm's length arrangement with the publisher and that the companies' involvement went beyond the provision of finance. The average invitee would reasonably expect the agenda to discuss, inter alia, the companies' products and thus be categorized under the Code as promotional in this regard.

The Panel noted that it was also possible that the complainant had been invited by postal invitation or telephone. There was no way of knowing whether this was so and precisely what had transpired. The Panel noted that whilst representatives had delivered invitations, the complainant had stated that he/she had stopped meeting representatives some years ago.

The Panel noted that all meetings had to comply, inter alia, with Clause 19 of the Code and have a clear educational content. The Panel noted that each presentation was accompanied by speaker notes. The Chair's introductory presentation discussed the complexity of the current prescribing environment including cost. The first presentation discussed diagnosis including detailed case scenarios. The second presentation 'Understanding the spectrum of different glucose-lowering drugs available' outlined the advantages and disadvantages and discussed each class of medicine. Pioglitazone was discussed and within the DPP-4 section linagliptin, saxagliptin, sitagliptin and vildagliptin. Two slides compared linagliptin with glimepiride in relation to their effect on HbA1c and weight change. Exenatide and insulin detemir were discussed in relation to GLP-1 receptor agonists and insulin in combination. The presentation concluded with a discussion of published guidance on the management of hyperglycaemia (NICE, QUIPP etc) and concluded with a take-home message slide which featured the statement 'However, the choice of agent depends on the specific circumstances and needs of the person with type 2 diabetes'. The third presentation, which discussed the relationship between diabetes, glucose-lowering drugs and cardiovascular (CV) disease, summarized CV outcomes of the major clinical trials. It featured a trial which compared the glucose-lowering efficacy and risk of CV events of certain sulphonylureas. Cardiovascular outcome data for liraglutide, saxagliptin and exenatide and linagliptin were discussed. The last section briefly summarized CV data for certain older glucoselowering therapies including pioglitazone and insulin glargine. The final presentation discussed monitoring and reviewing diabetics and their therapies and referred to medicines across all classes in relation to renal impairment. One slide favourably compared the clinical characteristics (dose adjustment, monitoring etc) of linagliptin with other DPP-4 inhibitors.

The Panel noted that the introduction to the speakers' briefing document stated that in addition to examining the key complexities of type 2 diabetes in clinical practice, the meetings aimed to provide information on the role of linagliptin and specifically in potentially reducing the

management complexity of this condition. The Panel considered that such an aim was not necessarily unacceptable so long as the meetings and advertisements about them complied with the Code. The Panel noted its comments above about the impression given by the invitation. The Panel also noted that the detailed speakers' briefing in relation to the individual presentations appeared balanced and only mentioned linagliptin once.

The Panel noted the clear educational content of the meeting as set out above and ruled no breach of Clause 19.1. The Panel noted its comments above about the role of the companies, the publisher and the programme committee as set out in the invitations. Clause 19.3 related solely to sponsorship and in that regard the Panel considered that the companies' sponsorship had been disclosed on the invitations and on the slides; no breach of Clause 19.3 was ruled.

It was not necessarily unacceptable for a questionnaire to enquire about a delegate's current and future prescribing decisions so long as it complied with the Code. Delegates did not have to provide the information. The Panel also noted that contrary to the complainant's account, the companies submitted that no representatives had entered the meeting room. It was not possible to determine where the truth lay. Whilst the parties' accounts differed, the Panel noted that it was not necessarily unacceptable for representatives to enter the main meeting room in relation to the meeting at issue.

The Panel noted that it had no way of knowing what was actually said by the speakers at the meeting in question. The Panel considered that the meeting was promotional for the companies' products mentioned. However, bearing in mind the impression given by the invitations as outlined above the Panel did not consider that its promotional nature was disguised as alleged; no breach of Clause 12.1 was ruled.

Noting its rulings above, the Panel ruled no breach of Clause 9.1.

During its consideration of this case the Panel noted that invitees were advised that the meetings were sponsored jointly by Lilly and Boehringer Ingelheim and their promotional scope was thus not limited to products promoted by the Alliance. The Panel considered that the prescribing information for Byetta or a relevant link thereto ought to have been included on all materials. In addition prescribing information for Jentadueto ought not to have been limited to the presentations but should have appeared on the invitations. There was no allegation on these points. The Panel requested that the companies be advised of its view.

Complaint received 13 November 2012

Case completed 20 December 2012