

NOVO NORDISK v LILLY

Promotional meeting

Novo Nordisk alleged that a meeting organised by Lilly, 'Treating Type 2 Diabetes - What Are Our Options?', promoted Byetta (exenatide) off-licence, misled the audience in terms of its licensed clinical use and did not encourage its rational use. According to the invitation an external health professional would cover the topic of pre-diabetes and the 'evidence on how best to manage' the condition. Novo Nordisk noted the prominent Byetta logo on the front of the invitation and the prescribing information on the back and strongly believed that a presentation and discussion on pre-diabetes was inappropriate and implied a wider indication for Byetta than its licensed indication.

Although the logos of Lilly and Amylin were displayed, and the prominent Byetta trademark suggested that the meeting would discuss Byetta, Novo Nordisk did not believe the declaration of sponsorship was sufficiently prominent from the outset. It was not clear whether Amylin had sponsored the meeting. Further, the declaration itself was not sufficiently detailed as to reflect the nature of each company's involvement in the meeting.

Given the above, and the fact that the invitation did not provide a clear indication as to the content or the form of the meeting and that there were spelling mistakes, Novo Nordisk believed high standards had not been maintained.

The detailed response from Lilly is given below.

The Panel noted that the invitation was accompanied by a letter on Lilly headed notepaper which described the meeting as promotional and sponsored by Lilly. The Panel also noted that Lilly accepted that the meeting was promotional in nature.

The Panel noted that the presentation at issue discussed, *inter alia*, the causes, diagnosis and management of pre-diabetes. The only reference to antidiabetic medicines was a bullet point on one slide which read 'Meds?? Metformin?? Glitazone????'. The Panel accepted that the presentation was informative and likely to have addressed delegates' educational needs. Nonetheless, it was an integral part of a promotional meeting; this was certainly the clear impression given by the invitation which bore the Byetta logo and included prescribing information. In the Panel's view, both recipients of the invitation and delegates would inevitably associate Byetta with pre-diabetes. The presentation was likely to prompt questions about the treatment of pre-diabetes with Byetta. The Panel considered that the presentation on pre-diabetes, as an integral

part of a Byetta promotional meeting, meant that the promotion of Byetta was inconsistent with its marketing authorization. A breach of the Code was ruled. The invitation and meeting were misleading about Byetta's licensed indication and consequently did not encourage its rational use. Breaches of the Code were ruled.

The Panel noted that the supplementary information to the Code required the declaration of sponsorship to be sufficiently prominent such that readers of sponsored material were aware of it at the outset. The Panel considered that from the outset anyone receiving an invitation could be under no doubt that the promotional meeting to which they were being invited was organised by Lilly. No breach of the Code was ruled on this point.

It was not clear from the front page of the invitation why the Amylin corporate logo appeared. The Panel noted Lilly's submission that it indicated ownership of the product copyright. The only explanation appeared on the outside back cover beneath the prescribing information which stated that Byetta was a trademark of Amylin Pharmaceuticals Inc. Lilly submitted that Amylin had no role in Lilly's activities in the UK. The Panel considered that from the inclusion of the Amylin logo without explanation, potential delegates might assume that Amylin had some role in the arrangements and that was not so. Readers would not know from the outset that Amylin was a pharmaceutical company. However Amylin had not sponsored the meeting as it had no role whatsoever. The Panel considered that the position could have been made clearer but Lilly had not failed to meet the requirements of the Code; no breach was ruled.

The Panel did not consider that the invitation itself failed to meet high standards due to its content and spelling mistake as alleged. No breach was ruled.

Novo Nordisk Limited complained about a promotional meeting organized by Eli Lilly and Company Limited. Inter-company dialogue had failed to resolve matters.

COMPLAINT

Novo Nordisk stated that Lilly had organised a promotional meeting for 7 July 2010 entitled 'Treating Type 2 Diabetes - What Are Our Options?'. According to the four page invitation (ref UKBYT00414) an external health professional would cover the topic of pre-diabetes. The invitation stated this presentation would cover the 'evidence on how best to manage' the condition.

Novo Nordisk considered that the meeting promoted Byetta (exenatide), given the prominent Byetta logo on the front of the invitation and the prescribing information for it on the back. Byetta was a reasonable therapeutic choice for the treatment of pre-diabetes (Rosenstock *et al* 2010). However the current licensed indication for Byetta was the treatment of type 2 diabetes mellitus, when used in combination with metformin and/or a sulphonylurea.

Novo Nordisk strongly believed that a presentation and discussion on pre-diabetes was inappropriate at a Byetta promotional meeting and implied a wider indication for the medicine than its licensed indication. Novo Nordisk alleged that the meeting promoted Byetta off-licence, misled the audience in terms of its licensed clinical use and did not encourage its rational use in breach of Clauses 3.2, 7.2 and 7.10 of the Code.

Novo Nordisk also believed the declaration in relation to Lilly's involvement in this meeting was not sufficiently prominent. Although the logos of Lilly and Amylin were displayed on page 1 of the invitation, which implied these companies were involved in the meeting, and the Byetta trademark was extremely prominent on page 1, which suggested that the meeting would discuss Byetta, there was no declaration regarding the input of either of these companies on page 1, and as such Novo Nordisk did not believe the declaration was sufficiently prominent from the outset in breach of Clause 9.10.

In relation to the declaration of sponsorship on page 2, Novo Nordisk believed the location of the declaration and use of a smaller font size than the font size used in the main body of the invitation on page 2 constituted a further breach of Clause 9.10, as it was not sufficiently prominent.

Further, the declaration on page 2 'This meeting is organised by Eli Lilly and Company Limited' did not provide sufficient clarity as to the input of Lilly and Amylin in relation to this meeting. The declaration did not refer to Amylin's involvement; although the Amylin logo was displayed at the foot of pages 1 and 2 it was not clear whether Amylin had sponsored the meeting. Novo Nordisk alleged a breach of Clause 9.10.

Novo Nordisk considered that the declaration itself did not provide sufficient information as to the involvement of Lilly and Amylin in terms of the meeting content. Had they merely sponsored the meeting, or had they produced the actual content? As such, Novo Nordisk believed this constituted a further breach of Clause 9.10.

Given the above, and the fact that the invitation itself did not provide a clear indication as to the content, or the form of the meeting (the agenda only listed two presentations and a closing by the chairman, whereas the short description implied 'opportunity to discuss'...'arena to discuss'...'share

learning'), and there were spelling mistakes with regard to the venue, Novo Nordisk believed high standards had not been maintained in breach of Clause 9.1.

RESPONSE

Lilly explained that the meeting was organised by its local diabetes representative. The context, content, supporting materials and overall arrangements were consistent with the requirements of Clause 19 and ensured an appropriate balance between diabetes related education and the promotion of Byetta, which had a marketing authorization for the treatment of patients with type 2 diabetes mellitus who were already receiving metformin and/or a sulphonylurea.

The agenda was developed by Lilly in consultation with a recognised local thought-leader in diabetes. The representative asked him to suggest a topic which would be of interest and relevant to his peers which he could then present at the meeting; he considered pre-diabetes to be a suitable educational topic. Lilly also solicited interest from another local health professional to support the other topic, identified by Lilly, which involved the promotion of Byetta. As a consequence, the meeting was entitled 'Treating Type 2 Diabetes – What Are Our Options?'

The potential delegates were identified by the representative and invited on the basis of their interest in the management of diabetes in primary care and therefore included GPs, pharmacists, practice nurses and diabetic specialist nurses. The potential delegates were limited to health professionals and appropriate administrative staff in accordance with the requirements of the Code.

The representative sent the meeting invitation with a letter (on Lilly letterhead) which she had signed. The letter clearly and prominently indicated that the invitation was to a professional meeting sponsored (organised) by Lilly. The invitation was therefore clearly promotional and included the Byetta product logo and branding, incorporated the Byetta prescribing information and the Lilly and Amylin corporate logos. The invitation further stated and clarified, on page 2, that 'This meeting is organised by Eli Lilly and Company Limited'. Given the promotional nature of the meeting this statement clearly left no doubt in the reader's mind as to Lilly's role in its organisation and administration.

Only the first paragraph of the 'invitation' section, on page 2 of the invitation (which began with the words 'This meeting will give you...'), related to the presentation on pre-diabetes. The subsequent two paragraphs referred to the treatment of type 2 diabetes and the role of Byetta.

The Amylin logo was included on the invitation because Byetta was a trade mark of Amylin Pharmaceuticals Inc; however all the UK marketing rights were held by Lilly. The European Marketing

Authorization holder was Eli Lilly Nederland BV. Amylin therefore had no role in Lilly's activities in the UK.

The speaker was briefed to give a scientific presentation discussing the relevance of pre-diabetes in primary care. This briefing expressly required that he should not mention any Lilly products. His presentation concentrated on causes and associations with pre-diabetes, screening procedures, diagnosis and potential prevention. The presentation included forty-four slides within which the fourth bullet point on slide 41 questioned whether 'metformin' or glitazones' had a role in the management of this condition; Lilly did not have a marketing authorization for either of these products in the UK. The wording 'Meds??' was also included in this slide but obviously was a generic mention. The representative was present at the meeting and confirmed that there was no mention of Byetta during this talk. The slides were, of course, reviewed and approved by Lilly in advance of the meeting. A copy of the presentation was provided.

Whilst the invitation and agenda promoted Byetta, the content and context of this particular section of the meeting genuinely attempted to address the educational requirements of the audience and did not support, invite or suggest the use of glucagon-like peptide-1 (GLP-1) receptor agonists such as Byetta or liraglutide in the management of pre-diabetes.

In summary, Lilly submitted that its role in organising this meeting was clear. It rejected Novo Nordisk's allegations that the presentation, or the meeting as a whole, was in breach of the Code. The company denied breaches of Clauses 3.2, 7.2, 7.10, 9.1 and 9.10.

Lilly was cognisant of its responsibilities with respect to the Code and had ensured that the promotional activities of its representatives were consistent with this (including, without limitation, Clauses 3.2, 7.2, 7.10, 9.1 and 9.10) and of the highest standard and quality.

PANEL RULING

The Panel noted that Byetta was indicated for treatment of type 2 diabetes mellitus in combination with metformin and/or sulphonylureas in patients who had not achieved adequate glycaemic control on maximally tolerated doses of these oral therapies.

The front page of the invitation featured the meeting title 'Treating Type 2 Diabetes – What Are Our Options?' above details of the chair, speakers, timings and venue. Beneath these logistical details in very small font size appeared the statement 'To access a wide range of information and resources to support both you and your patients, please visit: www.lillydiabetes.co.uk'. The Byetta product logo appeared prominently in the bottom right hand

corner. The corporate logos for Lilly and Amylin appeared in the bottom left hand corner.

The inside front cover of the invitation, page 2, began 'This meeting will give you the opportunity to discuss Pre-Diabetes' and referred to its incidence, diagnosis and management. The introduction continued referring to how and when to use newer licensed medicines for type 2 diabetes. A detailed agenda appeared on page 3. There were two clinical presentations; the presentation at issue, 'Pre-Diabetes: There's a lot of it about' and 'Treating Type 2 Diabetes – What are Our Options?'. The Lilly and Amylin corporate logos appeared in the bottom right and left hand corners of pages 2 and 3 respectively. The statement 'This meeting is organised by Eli Lilly and Company Limited' appeared at the bottom of page 2 and prescribing information for Byetta appeared on the outside back cover. The back cover also contained the statement 'BYETTA (exenatide) is a trademark of Amylin Pharmaceuticals, Inc'.

The Panel noted that the invitation was accompanied by a letter on Lilly headed notepaper which described the meeting as promotional and sponsored by Lilly. The Panel also noted that Lilly accepted that the meeting was promotional in nature.

The Panel noted that the presentation at issue discussed the condition of pre-diabetes in relation to, *inter alia*, its causes, diagnosis and management. The management section discussed the prevention and treatment of pre-diabetes. The only reference to antidiabetic medicines was a bullet point on one slide which read 'Meds?? Metformin?? Glitazone????'. Other bullet points on the same slide referred to diet, lipids – 'statin if needed' - aspirin (if positive cardiac history) and retinopathy screening. The Panel accepted that the presentation was informative and was likely to have addressed delegates' educational needs. Nonetheless, it was an integral part of a promotional meeting; this was certainly the clear impression given by the invitation which bore the Byetta logo prominently on the front cover and included prescribing information. In the Panel's view, both recipients of the invitation and delegates would inevitably associate Byetta with pre-diabetes. The presentation was likely to prompt questions about the treatment of pre-diabetes with Byetta. This was especially so given that treatment of pre-diabetes was the subject of published debate and delegates might be aware of this. Novo Nordisk had referred to Rosenstock *et al* (published in June 2010) which assessed Byetta, *inter alia*, in patients with pre-diabetes. The Panel considered that the presentation on pre-diabetes, as an integral part of a Byetta promotional meeting, meant that the promotion of Byetta was inconsistent with its marketing authorization. A breach of Clause 3.2 was ruled. The invitation and meeting were misleading about Byetta's licensed indication and consequently did not encourage its rational use. Breaches of Clauses 7.2 and 7.10 were ruled.

The Panel noted that the supplementary information to Clause 9.10 required the declaration of sponsorship to be sufficiently prominent such that readers of sponsored material were aware of it at the outset. The Panel considered that the nature of the material was relevant when deciding whether the requirements of Clause 9.10 and its supplementary information were satisfied. The Panel considered that from the outset anyone receiving an invitation could be under no doubt that the promotional meeting to which they were being invited was organised by Lilly. The letter which accompanied the invitation was particularly clear in that regard. The invitation, which the Panel noted must stand alone under the Code, bore Byetta prescribing information and the Lilly corporate and product logos featured prominently on the front page. More details of Lilly's role appeared on page 2 which stated that the meeting was organised by Eli Lilly. Whilst it would have been preferable if these details had appeared on the front cover in the particular circumstances of this case the Panel did not consider that recipients would consider the invitation to be anything other than for a promotional meeting organised by Lilly. No breach of Clause 9.10 was ruled on this point.

The Panel noted the allegation about the Amylin corporate logo on the front page and page 2 of the invitation. It was not clear from the front page of the invitation why the Amylin corporate logo appeared. The Panel noted Lilly's submission that it indicated

ownership of the product copyright. The only explanation appeared on the outside back cover beneath the prescribing information which stated that Byetta was a trademark of Amylin Pharmaceuticals Inc. Lilly submitted that Amylin had no role in Lilly's activities in the UK. The Panel noted that it was Lilly's sole responsibility to ensure that the material, including the reference to Amylin, complied with the Code. The Panel considered that from the inclusion of the Amylin logo without explanation, potential delegates might assume that Amylin had some role in the arrangements and that was not so. Readers would not know from the outset that Amylin was a pharmaceutical company. However Amylin had not sponsored the meeting as it had no role whatsoever. The Panel considered that the position could have been made clearer but Lilly had not failed to meet the requirements of Clause 9.10 and thus no breach was ruled in that regard.

The Panel did not consider that the invitation itself failed to meet high standards due to its content and spelling mistake as alleged. No breach of Clause 9.1 was ruled.

Complaint received	9 July 2010
Case completed	6 September 2010
