# ANONYMOUS DOCTOR v LILLY and BOEHRINGER INGELHEIM

## Sponsored supplement

**An anonymous doctor complained about a journal supplement distributed with an issue of Progress in Neurology and Psychiatry. The material in question was described as a report from the 2008 UK Psychiatry Forum and as 'A Progress supplement sponsored by Eli Lilly and Boehringer Ingelheim'. Prescribing information for Cymbalta (duloxetine) and Zyprexa (olanzapine) was included.**

**The complainant noted that the supplement had been produced to look exactly like the actual journal. There was only a small, easily missed statement at the bottom of the supplement indicating sponsorship by a pharmaceutical company.**

**From the supplement it appeared that the UK Psychiatry Forum was a body of some significant standing which was alleged to be misleading. The forum was an independent body but the complainant was not aware that it held any major impact in psychiatry academia or otherwise. It was not of any regulatory significance or responsible for any nationally implemented guidelines.**

**The complainant stated that the actual event that was reported was questionable. At a Lilly promotional meeting in Spain last year (s)he had heard all the authors speak in exactly the same order, giving exactly the same talks as in the report. The complainant alleged that the supplement thus misreported the actual event. The material was misleading and appeared to be disguised promotion.**

**The complainant noted that the supplement detailed a case of atypical depression. According to the Cymbalta summary of product characteristics (SPC), it was not licensed for atypical depression. This was off-licence promotion.**

**The complainant alleged that the supplement, in its entirety, was misleading and it was disappointing that the journal concerned had allowed it to be printed. Furthermore, such actions brought disrepute to an industry at a time when transparency in the NHS and industry was vital to ensure trusting mutual collaborative practice that benefitted the service provided to patients.**

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

**The Panel noted that the material in question provided the proceedings of a promotional symposium run by Lilly and Boehringer Ingelheim at the time of the European College of Neuropsychopharmacology (ECNP) congress, in the form of a journal supplement. The 90 delegates to the Lilly and Boehringer Ingelheim symposium had all been sponsored to attend the ECNP meeting by the two companies and the speakers had been chosen by the companies. The titles of the presentations had been mutually agreed and Lilly and Boehringer Ingelheim had reviewed the final papers to ensure compliance with the Code. The concept for the supplement was derived by Lilly and Boehringer Ingelheim and the companies paid for its production and distribution. The companies had certified the material in accordance with the Code.**

**The Panel considered that Lilly and Boehringer Ingelheim were wholly responsible for their meeting and thus for any output from it. There was no strictly arm's length arrangement. The supplement contained four papers of which the first referred to duloxotine and the third to olanzapine.**

**The Panel considered that the material at issue was not a supplement 'sponsored by Eli Lilly and Boehringer Ingelheim' as stated on the front cover but a paid for insert detailing the proceedings of a company meeting which had promoted Cymbalta and Zyprexa. In their response the companies had described the meeting as promotional and referred to the document as a promotional item. The Panel considered that the sponsorship statement disguised the promotional nature of the material. The reference to the UK Psychiatry Forum added to the misleading impression of a wholly independent meeting report. It was not stated that the 2008 meeting of the UK Psychiatric Forum was, in effect, a closed meeting run by Lilly and Boehringer Ingelheim. In that regard the forum had no recognised national standing. The Panel considered that the material was disguised promotion as alleged. A breach of the Code was ruled.**

**The Panel noted that Cymbalta was indicated, *inter alia*, for the treatment of major depressive episodes and the companies' submission that atypical depression was a sub-type of major depressive disorder. The Panel considered that the insert thus did not promote Cymbalta for an unlicensed indication as alleged. No breach was ruled.**

**The Panel considered that presenting the output of a company run meeting as an independent supplement to a journal demonstrated apparent**

**poor knowledge of the requirements of the Code. Health professionals generally looked to medical journals as a source of independent information; where authors wrote on behalf of companies or as a result of the activities of pharmaceutical companies this must be made clear. In the Panel's view the majority of readers would have viewed the material at issue quite differently if they had known that it was the report of a promotional company meeting and that the UK Psychiatric Forum was, in fact, a small group of health professionals chosen by Lilly and Boehringer Ingelheim with the titles of the papers presented being mutually agreed. The Panel considered that the description and presentation of the insert was such as to reduce confidence in, and bring discredit upon the pharmaceutical industry. A breach of Clause 2 was ruled.**

An anonymous doctor complained about a journal supplement distributed with volume 13, issue 1 2009 of Progress in Neurology and Psychiatry. The material at issue was described as a report from the 2008 UK Psychiatry Forum and as 'A Progress supplement sponsored by Eli Lilly and Boehringer Ingelheim'. Prescribing information for Cymbalta (duloxetine) appeared on the back cover and that for Zyprexa (olanzapine) appeared on the inside back cover.

## COMPLAINT

The complainant noted that the supplement had been produced to look exactly like the actual journal. There was only a small, non-prominent and easily missed statement at the bottom of the supplement indicating sponsorship by a pharmaceutical company.

On picking up the supplement it was misleading as it appeared that the UK Psychiatry Forum was a body of some significant standing. The forum was an independent body but the complainant was not aware that it held any major impact in psychiatry academia or otherwise. It was certainly not of any regulatory significance or responsible for any nationally implemented guidelines. A junior doctor reading the report might be misled as to its significance.

The complainant stated that the actual event that was reported was questionable. The complainant was in Barcelona last year and heard all the authors speak at a Lilly promotional meeting in exactly the same order, giving exactly the same talks that were repeated in this report. The complainant noted that this entire meeting was reported to have taken place as a forum of this body on the same dates and at the same place as the European College of Neuropsychopharmacology (ECNP) Lilly promotional symposium for UK doctors. The complainant alleged that the supplement thus misreported the actual event. The material was misleading and appeared to be disguised promotion.

The complainant noted that the supplement detailed a case of atypical depression. According to the Cymbalta summary of product characteristics (SPC), it was not licensed for atypical depression. This was off-licence promotion in breach of Clause 3.2.

The complainant alleged that the supplement, in its entirety, was misleading and it was disappointing that the journal concerned had allowed it to be printed. Furthermore, such actions brought disrepute to an industry at a time when transparency in the NHS and industry was vital to ensure trusting mutual collaborative practice that benefitted the service provided to patients.

The complainant alleged breaches of Clauses 2, 3.2 and 12.1 of the Code.

## RESPONSE

Lilly and Boehringer Ingelheim stated that the supplement was a promotional item that was clearly labelled to indicate that it had been sponsored by the two companies. This was stated prominently on the front cover: 'A Progress supplement sponsored by Eli Lilly and Boehringer Ingelheim. Abbreviated prescribing information can be found on pages 11 and 12'; an additional sponsorship statement appeared underneath the abbreviated prescribing information on the back cover. Lilly and Boehringer Ingelheim therefore did not consider that the complainant's contention of 'a small non-prominent and easily missed statement at the bottom of the supplement indicating sponsorship by a pharmaceutical company' was correct. The companies presumed this allegation referred only to the final page of the item, where the font size under the prescribing information was smaller; they did not consider that readers were likely to miss the statement on the front cover.

The cover and layout of the supplement was consistent with the journal as stated by the complainant. This, however, was common practice with most journal supplements and was not unique to this one. Pharmaceutical companies commonly sponsored supplements and in the UK the British Journal of Psychiatry and the Journal of Psychopharmacology (amongst many others) regularly produced supplements that were included within the mailing of issues of the journal.

With regard to the allegation that the term UK Psychiatry Forum was misleading and that junior doctors might be misled as to its significance, the companies noted that the supplement was titled 'A report from the 2008 UK Psychiatry Forum' on the front cover. In the introduction it was stated that the meeting of the forum was held in Barcelona on 29 August 2008. The forum thus referred to the gathering of a group of health professionals who attended this meeting. The use of 'forum' was meant to convey the essence of the term meeting rather than ascribe any importance to the group of clinicians who took part in the forum. No statement

was made relating to the importance or significance of this group in any manner. The speakers at the meeting were, however, described as 'an eminent faculty' and were named in the introduction. The chairman concluded his introduction with the hope the reader found the report interesting and useful in their clinical practice. The companies did not consider that any of the above would lead the reader to conclude that the UK Psychiatry Forum was a body of some significant standing as suggested by the complainant. No statement was made that could lead the reader to conclude that the forum had any regulatory significance or was responsible for any nationally implemented guidelines.

The companies noted the complainant's statement that the actual event that was reported was questionable. The introduction section on page 2 described the event as a 'symposium' from which the papers in the supplement were summarised. Details of the 'eminent faculty' were also given in the introduction and included some highly respected clinicians and academics. The complainant was correct in his/her assertion that this symposium was an Eli Lilly/Boehringer Ingelheim promotional meeting in Barcelona held during the 2008 ECNP congress. Although further details of the event might have aided greater clarity the companies did not accept that this amounted to a breach of Clause 12.1. The supplement was clearly labelled as being sponsored.

The companies noted the complainant's allegation of a breach of Clause 3.2. In one of a series of cases of patients with depression and anxiety, the author stated that the patient was likely to have had 'atypical major depressive disorder'. Lilly and Boehringer Ingelheim denied that any off-licence promotion had taken place. Cymbalta was licensed for major depressive episodes as was stated in the prescribing information. The Diseases and Statistics Manual of Mental Disorders IV Text Revision (DSM-IV-TR), a widely used manual for diagnosing mental disorders, defined atypical depression as a subtype of depression or dysthmia, characterised by atypical features. In addition, in the World Health Organisation's International Classification of Diseases (ICD-10) atypical major depressive disorder would fall in the category F32 (depressive episode) or F33 (recurrent depressive disorder). The companies contended that these diagnostic manuals made clear that atypical depression was a subtype of major depressive disorder. The item clearly stated a diagnosis of 'atypical major depressive disorder' which was consistent with the Cymbalta SPC; Cymbalta was licensed for all forms of major depressive disorder.

The companies disagreed with the complainant's allegation that the supplement was misleading in its entirety; no part of the supplement was misleading. It was clearly stated to be an eminent faculty report which contained relevant clinical data in a number of psychiatric illnesses, data which the companies hoped might be useful to clinicians.

Lilly and Boehringer Ingelheim did not agree that the sponsorship of the supplement, its content or dissemination was likely to bring disrepute to the industry.

In summary, the companies did not consider that there was substance to the complainant's allegations of breaches of Clauses 2, 3.2 or 12.1.

Lilly and Boehringer Ingelheim provided copies of the invitation, agenda and presentations given at the meeting in Barcelona. Ninety clinicians sponsored by Lilly and Boehringer Ingelheim to attend the ECNP congress in Barcelona attended the symposium and this was the group that was referred to as the UK Psychiatric Forum participants. There was no obligation to attend the UK psychiatric meeting, however the invitees were given an agenda that allowed them to attend this meeting on 29 August that took place in a closed meeting room in their hotel in Barcelona. The faculty to deliver presentations was brought together by Lilly/Boehringer Ingelheim to present lectures to the participants on the basis of their scientific and academic abilities, with each lecture being of 20 minutes. The majority of the faculty were internationally published authors. The supplement concept was derived by Lilly/Boehringer Ingelheim and a fee was paid to the publisher of Progress in Neurology and Psychiatry for the production and dissemination of the supplement. A medical writer attended, as reported in the supplement, to draft the first versions of the papers based on the presentations. The content of the presentations was not influenced by Lilly/Boehringer Ingelheim, although the titles for the talks were mutually agreed to reflect the relevant expertise of the speakers and clinicians. The final versions of the papers were completed and approved by the authors and at this stage the sponsoring companies viewed the papers to ensure compliance with the Code but not to exert any other editorial control. The final promotional item was reviewed and certified in accordance with the Code prior to distribution.

## PANEL RULING

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided, in relation to material aimed at health professionals, that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.

The Panel noted that the material in question provided the proceedings of a promotional symposium run by Lilly and Boehringer Ingelheim at the time of the ECNP congress, in the form of a journal supplement. The 90 delegates to the Lilly and Boehringer Ingelheim symposium had all been sponsored to attend the ECNP meeting by the two companies and the speakers had been chosen by the companies. The titles of the presentations had been mutually agreed and Lilly and Boehringer Ingelheim had reviewed the final papers to ensure compliance with the Code. The concept for the supplement was derived by Lilly and Boehringer Ingelheim and the companies paid for its production and distribution. The companies had certified the material in accordance with the Code.

The Panel considered that Lilly and Boehringer Ingelheim were wholly responsible for their meeting and thus for any output from it. There was no strictly arm's length arrangement. The supplement contained four papers: 'Depression and comorbid anxiety: case histories', 'The clinical challenge of bipolar mixed states', 'Effectiveness of antipsychotic drugs in first-episode schizophrenia and schizophreniform disorder' and 'Does patient choice improve long-term outcomes?'. The first paper referred to duloxotine and the third to olanzapine.

The Panel considered that the material at issue was not a supplement 'sponsored by Eli Lilly and Boehringer Ingelheim' as stated on the front cover but a paid for insert detailing the proceedings of a company meeting which had promoted Cymbalta and Zyprexa. In their response the companies had described the meeting as promotional and referred to the document as a promotional item. The Panel considered that the sponsorship statement disguised the promotional nature of the material. The reference to the UK Psychiatry Forum added to the misleading impression of a wholly independent meeting report. It was not stated that the 2008 meeting of the UK Psychiatric Forum was, in effect, a closed meeting run by Lilly and Boehringer Ingelheim. In that regard the forum had no recognised national standing. The Panel considered that the material was disguised promotion as alleged. A breach of Clause 12.1 was ruled.

The Panel noted that Cymbalta was indicated, *inter alia*, for the treatment of major depressive episodes. In the paper on 'Depression and comorbid anxiety; case histories' the first case history presented was of a patient with atypical major depressive disorder. The Panel noted the companies' submission that this was a sub-type of major depressive disorder. The Panel considered that the insert thus did not promote Cymbalta for an unlicensed indication as alleged. No breach of Clause 3.2 was ruled.

The Panel considered that presenting the output of a Lilly and Boehringer Ingelheim run meeting as an independent supplement to a journal demonstrated apparent poor knowledge of the requirements of the Code. Health professionals generally looked to medical journals as a source of independent information; where authors wrote on behalf of companies or as a result of the activities of pharmaceutical companies this must be made clear. In the Panel's view the majority of readers would have viewed the material at issue quite differently if they had known that it was the report of a promotional company meeting and that the UK Psychiatric Forum was, in fact, a small group of health professionals chosen by Lilly and Boehringer Ingelheim with the titles of the papers presented being mutually agreed. The Panel considered that the description and presentation of the insert was such as to reduce confidence in, and bring discredit upon the pharmaceutical industry. A breach of Clause 2 was ruled.

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