CASE AUTH/2850/6/16

ANONYMOUS, NON-CONTACTABLE v SUNOVION

Disparagement at a meeting

An anonymous, non-contactable complainant complained about comments made at a meeting organised by Sunovion Pharmaceuticals Europe. The meeting was one of a series for clinical psychiatrists and related professionals. Sunovion marketed Latuda (lurasidone) an antipsychotic used in the treatment of schizophrenia.

The complainant alleged that a presenter's suggestion that anyone should feel guilty if they prescribed olanzapine disparaged the medicine and the psychiatrists who prescribed it. An experienced psychiatrist knew that for some service users, olanzapine was actually the best treatment for them. The complainant stated that everyone was different and they should be free to take all factors into account and to prescribe within their clinical judgement as recommended by national guidelines without being made to feel guilty.

The detailed response from Sunovion is given below.

The Panel noted that a Sunovion employee gave a presentation which included comparisons of Latuda with other atypical antipsychotics. Although weight gain was referred to as a common side-effect of Latuda, data was presented which showed that weight gain with olanzapine was greater. Sunovion's response included comments from two company attendees who remembered that the presenter had questioned why clinicians were continuing to use olanzapine. The company attendees referred to these comments being made in relation to changes in weight. The complainant made no mention of weight gain in this context. The Panel noted the difficulty of dealing with allegations regarding what was said at a meeting. However, on the evidence before it, the Panel considered that, on the balance of probabilities, the presenter had suggested clinicians should feel guilty if they prescribed olanzapine. This was a medicine licensed to treat schizophrenia and clinically significant weight gain was listed as an adverse event. The company acknowledged that the presenter had been disparaging although he/she had no recollection of being so.

The Panel considered that comments about clinicians feeling guilty about prescribing any medicine for its licensed indication disparaged those health professionals and their clinical and scientific opinions. The Panel therefore ruled a breach of the Code. The Panel also ruled that high standards had not been maintained.

The presenter was not a representative as defined by the Code and thus the Panel ruled no breach in this regard.

An anonymous, non-contactable complainant complained about a meeting organised by Sunovion Pharmaceuticals Europe Ltd in Cardiff in April 2016 and in particular about comments made by a company presenter. The meeting was one of the 'HOPE' ('honest opinions personal experiences') series of meetings for clinical psychiatrists and related professionals. Sunovion marketed Latuda (lurasidone) an antipsychotic agent used in the treatment of schizophrenia.

COMPLAINT

The complainant stated that during a presentation at the 'HOPE' meeting the company employee suggested that anyone should feel guilty if they prescribed olanzapine. The complainant alleged that this disparaged the medicine and the psychiatrists who prescribed it. An experienced psychiatrist knew that for some service users, olanzapine was actually the best treatment for them. The complainant stated that everyone was different and they should be free to take all factors into account and to prescribe within their clinical judgement as recommended by the National Institute for Health and Care Excellence (NICE) without being made to feel guilty for their choice.

When writing to Sunovion, the Authority asked it to respond in relation to Clauses 8.2, 9.1 and 15.2.

RESPONSE

Sunovion submitted that the 2016 'HOPE' meeting series comprised three high quality educational meetings held in April. A total of 142 delegates attended the series; 71 attended the Cardiff meeting. The 'HOPE' programme had run since 2014 and feedback from delegates had been very good; Sunovion received overwhelming positive comments on the quality and content of these meetings eg 92% of delegates who attended one of the three meetings in 2016 and completed an event feedback form, rated the overall impression of the event programme as excellent or good.

The overall approach for the 'HOPE' meetings was to inform, educate and encourage discussion among an audience of peers. In this spirit, exchanges were dynamic and interactive, and reflected the speakers' profound involvement in the areas discussed. Delegate feedback on this format was very positive; one delegate at the Cardiff meeting commented in their feedback form that 'The best presentations were when there was the most interactivity with the audience'.

The meeting content was highly scientific; it included efficacy and safety data on a range of antipsychotic agents including Latuda and olanzapine and referred to authoritative independent recommendations.

Sunovion provided a copy of the meeting invitation, agenda and the presentation. The presentations, agenda and invitations were certified by Sunovion.

The Sunovion presenter was one of seven speakers and this presentation lasted 45 minutes from a total presentation content of 3 hours and 45 minutes.

Sunovion stated that the presenter was certain that he/she would not have deliberately stated or intended to imply that doctors should feel guilty about prescribing olanzapine. The presenter clearly understood that there were circumstances where the use of olanzapine was entirely appropriate and he/she had often prescribed it.

The presentation, 'A Review of Latuda (lurasidone) efficacy & tolerability registration studies', included results from published clinical trials involving Latuda, olanzapine and a number of other licensed medicines. In addition, one slide referenced the Maudsley Prescribing Guidelines in Psychiatry. The presentation contained only published/data on file scientific information and made no claims regarding prescribing olanzapine or otherwise. The presenter believed that where any informal verbal statement regarding the use of olanzapine was made, it was in reference to weight gain. If any concern had been raised about the impression given by his/her comments at the meeting it would have immediately been corrected.

Sunovion submitted that it had interviewed two other company attendees; their recollections of dialogue made during the presentation were as follow:

> Participant A: The presenter made a remark along the lines of 'how can you clinicians consciously continue to prescribe olanzapine' phrased in context of weight gain, the remark was made in the course of the speakers' commentary and not in response to a question from the audience and a speaker at his table noted that 'you should not say that'.
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> Participant B: A statement was made by the presenter along the lines of 'for those who feel guilty prescribing olanzapine'; this was in the context of weight loss. A speaker who shared a table with me gave me a look, made a comment about the ABPI clauses and said 'can he say that?'.

Sunovion stated that all materials for the Cardiff meeting were reviewed and certified as compliant with the Code. Whilst the presenter had no recollection of commenting on the prescribing of olanzapine, and was certain that no comment would have been intentionally made, it was apparent that other company attendees recollected that something was said that could have been interpreted in a way that was not intended. This appeared to be a single sentence in a 45 minute presentation and within the broader context of an 8 hour event of seven presenters.

Sunovion noted that 81% of delegates who attended one of the three 'HOPE' meetings in 2016 and completed an event feedback form, rated the presentation as very useful or useful and a further 13% as fairly useful.

Sunovion stated that the presenter did not intend to disparage the practice of health professionals and apologised for any unintended consequences.

On the basis of the investigation described above, Sunovion acknowledged a breach of Clause 8.2. The presentation was developed by the speaker with other Sunovion Pharmaceuticals Europe and Sunovion staff and he/she was therefore very familiar with the content and objectives of the session. In addition, in advance of the first 2016 'HOPE' meeting, the presenter attended a full run through by all speakers.

With reference to Clause 9.1, Sunovion stated that this was an isolated one-off comment, at a single meeting in a series of high quality educational events which had been well received by clinicians. All content and materials were reviewed and certified and none contained or advocated anything which disparaged another product or competitor; Sunovion submitted that all 'HOPE' materials were accurate, fair and balanced and on that basis it refuted any breach of Clause 9.1.

Sunovion also refuted any breach of Clause 15.2 which referred specifically to high standards on the part of representatives. The presenter's role did not meet the Code definition of a representative ie 'a representative calling on members of the health professions and other relevant decision makers in relation to the promotion of medicines'.

Sunovion stated it was committed to self-regulation and strongly supported the Code. The company accepted responsibility for the incident described above and greatly regretted this unplanned and informal comment at a highly interactive meeting. Sunovion reiterated that there was no intention to disparage a third party.

PANEL RULING

The Panel noted that the meeting was organised by Sunovion and it was clearly a promotional meeting. The presentation 'A review of Latuda efficacy & tolerability registration studies' included comparisons of Latuda with other atypical antipsychotics. Although weight gain was referred to as a common side-effect of Latuda, data was presented which showed that weight gain with olanzapine was greater. Latuda prescribing information was included on the agenda, invitation and the presentation. It appeared from the company response that two company attendees remembered that the presenter had raised the issue of continuing to use olanzapine and questioning why clinicians were continuing to do this. The company attendees referred to these comments being made in relation to changes in weight. The complainant alleged that the presenter suggested that clinicians should feel guilty if they prescribed olanzapine but made no mention of weight gain in this context. The Panel noted the difficulty of dealing with allegations regarding what was said at a meeting. However, on the evidence before it, the Panel considered that, on the balance of probabilities, the presenter had suggested clinicians should feel guilty if they prescribed olanzapine. This was a medicine licensed to treat schizophrenia and clinically significant weight gain was listed as an adverse event. Sunovion acknowledged that the presenter had been disparaging although he/she had no recollection of being so.

The Panel considered that comments about clinicians feeling guilty about prescribing any medicine for its licensed indication disparaged those health professionals and their clinical and scientific opinions. The Panel therefore ruled a breach of Clause 8.2. The Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The presenter was not a representative as defined by Clause 1.7 and thus Clause 15.2 did not apply and the Panel ruled no breach.

Complaint received **13 June 2016**

Case completed **13 July 2016**