CASE AUTH/2833/4/16

ALK-ABELLÓ v BAUSCH & LOMB

Breach of undertaking

ALK-Abelló alleged that Bausch & Lomb had breached its undertaking given in Case AUTH/2802/11/15 for a second time.

ALK-Abelló stated that the material at issue was a presentation given by Bausch & Lomb to an allergy group in March 2016. The meeting was sponsored by Bausch & Lomb. A copy of the agenda was provided.

As the complaint concerned an alleged breach of undertaking it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

The detailed response from Bausch & Lomb is given below.

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future. It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/2802/11/15 ALK-Abelló had complained in November 2015 that the claim 'Emerade offers a new higher dose …', which appeared in a Pulse Quick Guide, implied that a new higher dose of Emerade had been launched within the last 12 months. The Panel noted that this was not so. The Emerade 500mcg summary of product characteristics (SPC) stated that the date of the first marketing authorization/renewal of authorization was 3 January 2013. A breach of the Code was ruled which was accepted by Bausch & Lomb; the company's undertaking, signed in December 2015, stated that September 2015 was the last date the material was used or appeared.

In Case AUTH/2817/12/15, ALK-Abelló complained in December 2015 that Emerade continued to be described as 'new' on the product website. The Panel considered that Bausch & Lomb had failed to comply with its undertaking given in Case AUTH/2802/11/15 and breaches of the Code were ruled.

Turning to the case now before it, Case AUTH/2833/4/16, the Panel noted that a consultant had presented an update on adrenaline auto injectors at a third party meeting. One of the presentation slides was headed 'New Design' above a picture of Emerade 500mcg. The Panel noted Bausch & Lomb's submission that it had no knowledge of the meeting nor of the involvement of the consultant. The consultant was not authorized by Bausch & Lomb to carry out field based activities and had been restricted to non-field based activities.

The Panel noted that the agenda which had been distributed to delegates stated that the consultant was from Bausch & Lomb and that 'You are all invited for complementary drinks immediately following the meeting, sponsored by Bausch and Lomb'. The meeting chair confirmed that prior to the meeting, but after the agenda had been circulated, the consultant had contacted him/her and confirmed that he/she was attending and presenting in a personal capacity. The consultant asked the chair to announce that his/her presentation and invitation for drinks afterwards was a personal one and not sponsored by Bausch & Lomb. The chairman stated that this had been done at the beginning and end of the presentation. In addition Bausch & Lomb provided a copy of an email from the consultant which stated that he/she had reiterated the chair's explanation before speaking. The Panel was not provided with a copy of the invitation to the meeting.

The consultant's explanation of the arrangements appeared to be inconsistent with the agenda. The consultant explained that he/she was invited to present on how current prescription regulations during medical emergencies could be interpreted which was subsequently extended to include the history and background of adrenaline auto-injector (AAI) design when another speaker did not attend. It was unclear when the previous speaker pulled out of the meeting, however this person's details did not appear on the agenda.

The Panel considered that it should have been possible to circulate a new agenda by email prior to the meeting and also at the meeting itself to make the position clear. ALK-Abelló did not refer to the change in arrangements. In addition it was apparent that the consultant had ample opportunity to raise this matter earlier than the day before the meeting when he/she saw the agenda.

Attendees at the meeting had been provided with material which did not comply with the Code. The question to be considered was whether Bausch & Lomb was responsible under the Code when the presenter, who was a consultant for Bausch & Lomb, was apparently acting in contravention of instructions from the company. The Panel considered that given there was a consultancy agreement between the parties at the time of the meeting and the impression given by the agenda and slides, Bausch & Lomb was responsible for the consultant's actions. The statement from the chair was insufficient to alter the company's responsibility in this regard. One of the slides referred to Emerade's 'New design'. The meeting was held after Bausch & Lomb had given its undertakings

in Cases AUTH/2802/11/15 and AUTH/2817/12/15. Thus there had been a failure to comply with those undertakings. High standards had not been maintained. Breaches of the Code were ruled. The Panel noted its concerns about the clarity of the instructions given to the consultant but nonetheless considered that overall the company had been very badly let down by its consultant. The company had attempted to restrict the consultant's activities. The Panel noted the importance of complying with undertakings and that it had ruled that high standards had not been maintained. The Panel considered that in the exceptional circumstances of this case and on balance, Bausch & Lomb's failure to comply with its undertakings did not warrant a ruling of a breach of Clause 2 and thus no breach of that clause was ruled.

ALK-Abelló Ltd alleged that Bausch & Lomb had breached its undertaking given in Case AUTH/2802/11/15 for a second time.

Case AUTH/2802/11/15 (ALK-Abelló v Bausch & Lomb) concerned the use of the word 'new' to describe Emerade (adrenaline auto-injector [AAI]) when the product had been available for more than 12 months. A breach of the Code was ruled which was accepted by Bausch & Lomb. Case AUTH/2817/12/15 (ALK-Abelló/Director v Bausch & Lomb) concerned a breach of undertaking given that Emerade continued to be described as new on the product website.

ALK-Abelló stated that the material now at issue was a presentation given by Bausch & Lomb to an allergy group in March 2016. The meeting was sponsored by Bausch & Lomb. A copy of the agenda was provided.

COMPLAINT

ALK-Abelló noted that the Bausch & Lomb presentation included a slide headed 'New Design' beneath which was a prominent image of an Emerade auto-injector, despite the ruling in Case AUTH/2802/11/15. ALK-Abelló stated that it was particularly disappointing that this was the second time it had alleged a breach of undertaking.

As the complaint concerned an alleged breach of undertaking it was taken up by the Authority in the name of the Director as the Authority was responsible for ensuring compliance with undertakings.

When writing to Bausch & Lomb, the Authority asked it to respond in relation to Clauses 9.1 and 2 of the Code in addition to Clause 29 cited by ALK-Abelló.

RESPONSE

Bausch & Lomb submitted that the person named on the meeting agenda, as an employee of the company and who would present the update on adrenaline auto-injectors was not an employee of Bausch & Lomb UK or any member of its group. The named person was a third party that another part of the Bausch & Lomb group had an agreement with to consult and support marketing activities with Emerade. This agreement was implemented in March 2015 on the transfer of the sales and marketing rights of Emerade to Bausch & Lomb from a company where the named person had a role. This person had no rights to use the Bausch & Lomb name or act on behalf of the company outside of the terms of the consultancy agreement.

Bausch & Lomb stated that it was only on notification of the complaint that it knew of: any involvement by the company in the meeting held in March 2016; any arrangement between the organisers of the meeting and Bausch & Lomb; any attendance of any Bausch & Lomb personnel at the event; and the named individual's attendance. Bausch & Lomb submitted that the attendance at the meeting and use of the Bausch & Lomb name directly conflicted with the instructions provided by the company. The presentation given at the meeting was not approved by Bausch & Lomb.

The named individual was currently prohibited from attending any direct customer facing meetings and had been since the start of November 2015. Details were provided.

Since early November 2015, Bausch & Lomb had not instructed the named individual to carry out any activities on its behalf and was strictly prohibited from any face-to-face contact of the type facilitated by the meeting in question.

Bausch & Lomb stated that the named individual had confirmed that he/she did not attend or sponsor the meeting as a representative of Bausch & Lomb. The chairman and organiser of the meeting in question was made aware that the reference to Bausch & Lomb on the meeting agenda was inaccurate and this was disclosed from the platform to the attendees at the start of the meeting. This description of events had been confirmed as accurate by the chairman and organiser of the meeting.

Bausch & Lomb accepted that its relationship with the third party placed responsibility on Bausch & Lomb in the eyes of third parties. The company accepted that the named individual's attendance at the meeting and the agenda had given the impression to attendees that he/she represented Bausch & Lomb irrespective of the instructions provided. However, given the specific restrictions placed on the named individual by Bausch & Lomb, it did not foresee that he/she would contravene such instructions.

Bausch & Lomb's internal approval processes in respect of expenses was such that expense claims for an engagement such as the meeting in question must be pre-approved before they could be incurred. The named person was fully aware of this process and had used it on many occasions. Following the suspension he/she had not submitted any expenses for approval and therefore the company had no reason to believe that there had been a breach of the restrictions. The named person did not submit an expenses application in respect of the meeting in question or request permission to attend.

With the benefit of hindsight Bausch & Lomb now saw that potentially additional measures could

have been taken to ensure compliance with its instructions. However, at the relevant times, nothing in the named individuals' communications with the company or behaviour indicated an intention not to comply with the company's instructions.

Bausch & Lomb stated that it clearly took the named individual's actions extremely seriously.

With regard to the presentation given at the meeting, Bausch & Lomb stated that it was created without its knowledge and so there was no certificate approving it; it was not a Bausch & Lomb document.

Bausch & Lomb stated that the situation was deeply regrettable.

In response to a request for further information, Bausch & Lomb stated that the instruction not to engage in 'non-field based marketing activities' meant no customer contact face to face or otherwise and only if requested by Bausch & Lomb to be involved in any internal strategy discussions. The company had not instructed the named individual to take part in any activities non-field based or otherwise since November 2015.

Bausch & Lomb wrote to the named individual in November and December 2015. In addition, this position was reinforced by another named person from the third party.

With regard to pending field based activities the named individual was advised that all meetings and appointments should be handed over to the sales manager and that he/she should have no direct contact with the sales force. Bausch & Lomb sales teams were also advised to have no direct contact with the named individual who was compliant in handing over the relevant information on upcoming events and Bausch & Lomb had no reason to believe that this had changed.

Bausch & Lomb was not aware of the meeting in question prior to receiving the complaint letter. On writing to the named individual to request a response to a number of questions including about when the meeting arrangements were made the named individual stated that the meetings were held quarterly. He/she regularly attended these meetings and spoke. He/she was invited to give an update on how current prescription regulations during medical emergencies could be interpreted, a subject of current discussion amongst the group and an issue of interest to the individual. When another speaker had to pull out of the March date, he/she was asked to cover this slot. The individual agreed and extended the talk to include the history and background of AAI design.

Bausch & Lomb stated that its sales manager and the other named person from the third party had regular contact with the individual to monitor and ensure that he/she complied with the terms of the suspension. Bausch & Lomb submitted that there had been no claim on expenses from November 2015 which would indicate compliance with Bausch & Lomb's instruction.

Neither of these individuals were aware of this meeting. The first Bausch & Lomb became aware of this meeting was upon receipt of the complaint letter in April 2016. The individual stated that no one at Bausch & Lomb was aware of the meeting. He/she had never planned to attend in Bausch & Lomb's name or as its representative. Since leaving a previous company a number of years ago, he/she had continued to attend these meeting as a private individual, for educational and social reasons. A representative from another company was supposed to be in attendance and host the meeting, but was waylaid and did not make it.

The response to the question when did the named individual contact the meeting chairman and advise him that the reference to Bausch & Lomb on the agenda was inaccurate was that the chairman and organiser of the meeting, was made aware of the inaccuracy in the agenda prior to the meeting and the error in the agenda and Bausch & Lomb's non-involvement was further disclosed from the platform at the start of the meeting.

The individual's response to the question why an updated agenda was not provided to the delegates was that in hindsight that should have been the correct course of action, but instead the error was disclosed the following day by the chairman from the platform, before and during the meeting. He/she clearly explained that the individual was not there on behalf of Bausch & Lomb but as a personal member of the group. The individual also reiterated this before speaking and clarified and apologised for the error in the programme.

According to the individual the complementary drinks were organised between the sponsoring company and group organising the meeting.

Bausch & Lomb did not provide or have any knowledge of monies being paid for the drinks. No expenses were claimed from Bausch & Lomb. Bausch & Lomb assumed therefore that these were paid by the individual.

Bausch & Lomb submitted that it seemed that the named individual intentionally proceeded with this meeting without the knowledge or permission of Bausch & Lomb. He/she deliberately acted outside the scope of his/her authority and knowingly failed to comply with his/her contractual obligations. As a result, the company had taken immediate remedial action.

PANEL RULING

The Panel noted that a form of undertaking and assurance was an important document. Companies had to give an undertaking that the material in question and any similar material, if not already discontinued or no longer in use would cease forthwith and give an assurance that all possible steps would be taken to avoid similar breaches of the Code in the future (Paragraph 7.1 of the Constitution and Procedure). It was very important for the reputation of the industry that companies complied with undertakings.

The Panel noted that in Case AUTH/2802/11/15 ALK-Abelló had complained in November 2015 that the claim 'Emerade offers a new higher dose …', which appeared in a Pulse Quick Guide, implied that a new higher dose of Emerade had been launched within the last 12 months. The Panel noted that this was not so. The Emerade 500mcg summary of product characteristics (SPC) stated that the date of the first marketing authorization/renewal of authorization was 3 January 2013. A breach of Clause 7.11 was ruled which was accepted by Bausch & Lomb; the company's undertaking, signed in December 2015, stated that September 2015 was the last date the material was used or appeared.

In Case AUTH/2817/12/15 ALK-Abelló complained on 23 December 2015 that Emerade continued to be described as 'new' on the product website. The Panel considered that Bausch & Lomb had failed to comply with its undertaking given in Case AUTH/2802/11/15 and breaches of Clauses 2, 9.1 and 29 were ruled.

Turning to the case now before it, Case AUTH/2833/4/16, the Panel noted that a consultant had presented an update on adrenaline auto injectors at a third party meeting. The presentation mentioned EpiPen, JEXT, and Emerade with an emphasis on Emerade. Slide 8 of the presentation was headed 'New Design' above a picture of Emerade 500mcg. The Panel noted Bausch & Lomb's submission that it had no knowledge of the meeting nor of the involvement of the consultant. As a result of a separate conduct matter the consultant was not authorized by Bausch & Lomb to carry out field based activities. He/she was restricted to non-field based activities.

The Panel noted that the agenda which had been distributed to delegates stated that the consultant was from Bausch & Lomb and concluded by stating that 'You are all invited for complementary drinks immediately following the meeting, sponsored by Bausch and Lomb'. The meeting chair confirmed that prior to the meeting but after the agenda had been circulated the consultant had contacted him/her and confirmed that he/she was attending and presenting in a personal capacity The consultant asked the chair to announce that his/her presentation and invitation to go out for drinks afterwards was a personal one and was not sponsored by Bausch & Lomb. The email from the chair stated that he/she did this at the beginning and end of the presentation. In addition Bausch & Lomb provided a copy of an email from the consultant wherein he/she stated that he/she had reiterated the chair's explanation before speaking. The Panel was not provided with a copy of the invitation to the meeting.

The consultant's explanation of the arrangements appeared to be inconsistent with the agenda. The consultant explained that he/she was invited to present on how current prescription regulations during medical emergencies could be interpreted which was subsequently extended to include the history and background of AAI design when another speaker had to pull out/was waylaid. It was unclear when the previous speaker pulled out of the meeting, however his/her details did not appear on the agenda.

The Panel considered that it should have been possible to circulate a new agenda by email prior to the meeting and also at the meeting itself to make the position clear. ALK-Abelló did not refer to the change in arrangements. In addition it was apparent that the consultant had ample opportunity to raise this matter earlier than the day before the meeting when he/she saw the agenda.

The Panel considered that Bausch & Lomb had made it clear to the named individual that he/she was restricted to non-field based marketing activities in letters dated in November and December 2015. There was however no explanation of what Bausch & Lomb meant by non-field based activities. In its response to the Panel Bausch & Lomb referred to an apparently narrower prohibition on attending any direct customer facing meetings and no contact with customers face to face or otherwise. The Panel considered that the company could have been clearer about the nature of the prohibition in its aforementioned letters.

Attendees at the meeting had been provided with material which did not comply with the Code. The question to be considered was whether Bausch & Lomb was responsible under the Code for the activity when the presenter, who was a consultant for Bausch & Lomb, was apparently acting in contravention of instructions from the company. The Panel considered that given there was a consultancy agreement between the parties at the time of the meeting and the impression given by the agenda and slides, Bausch & Lomb was responsible for the consultant's actions. The statement from the chair was insufficient to alter the company's responsibility in this regard. One of the slides referred to Emerade's 'New design'. The meeting was held after Bausch & Lomb had given its undertakings in Cases AUTH/2802/11/15 and AUTH/2817/12/15. Thus there had been a failure to comply with those undertakings. The Panel therefore ruled a breach of Clause 29. High standards had not been maintained and a breach of Clause 9.1 was also ruled. The Panel noted its concerns about the clarity of the instructions given to the consultant but nonetheless considered that overall the company had been very badly let down by its consultant. The company had attempted to restrict the consultant's activities. The Panel noted the importance of complying with undertakings and that it had ruled a breach of Clause 9.1. The Panel considered that in the exceptional circumstances of this case and on balance, that Bausch & Lomb's failure to comply with its undertakings did not warrant a ruling of a breach of Clause 2 and thus no breach of that clause was ruled.

Complaint received **4 April 2016**

Case completed **31 May 2016**