

ANONYMOUS EX-EMPLOYEE v CEPHALON

Inappropriate hospitality and in-house feedback document

An anonymous ex-employee complained that, in 2009, Cephalon provided inappropriate hospitality to delegates it had sponsored to attend a European congress in Lisbon. The complainant referred to a congress feedback document which, *inter alia*, stated 'we then went to a few bars and to a club until 3am – a few good photos to prove it!!!'. The complainant also submitted that the document implied that sublingual Effentora (fentanyl) had been promoted before the marketing authorization for such use had been granted. The complainant further noted that the document referred to the differentiation between Effentora and ProStrakan's Abstral (fentanyl) and alleged that implied comparisons had been made that were incapable of substantiation and potentially misleading. The complainant considered that the document, which had not been approved as briefing material, gave a very poor impression; the representatives involved did not appear fully conversant with the Code and had failed to maintain high standards. Breaches of the Code were alleged, including a breach of Clause 2.

The detailed response from Cephalon is given below.

The Panel noted that the complaint had been prompted by an internal feedback document detailing the aspects of a congress in Lisbon to which Cephalon had sponsored thirteen health professionals. The document made much of the hospitality provided to customers with phrases such as 'Dinner was fantastic', 'great night again', 'took them clubbing' and 'we then went to a few bars and to a club until 3am – a few good photos to prove it!!!'. The document concluded with 'All the customers were really looked after and spoke positively about Effentora – lets make sure they start Rxing now!'. The Panel noted that the feedback document had been distributed within Cephalon including to sales teams. The Panel considered that recipients would read the document and assume that it represented accepted practice with regard to hospitality. The Panel considered that the feedback document was, in effect, briefing material which advocated a course of action which would be likely to lead to a breach of the Code. A breach of the Code was ruled.

The Panel considered that the impression given by the feedback document of a general party atmosphere, recorded on camera, was wholly unacceptable. In that regard the Panel considered that high standards had not been maintained. The Panel further considered that the references to the hospitality provided were such as to bring discredit upon the industry. Breaches of the Code were ruled including a breach of Clause 2.

Receipts from various restaurants and bars were provided. Restaurant costs ranged from £43 to £57/head. One bill was inflated as only 15 people attended but the 20 covers booked had to be paid for. Early morning bar bills included the purchase of spirits and cocktails. On one evening the group had watched fire-eaters and the feedback document implied that the evening finished at 3am.

Overall, the Panel considered that, on a cumulative basis, the hospitality provided went beyond subsistence. It appeared that the hospitality was not secondary to the main purpose of being in Lisbon ie to attend a congress. That one of the Cephalon employees photographed the group added to the overall impression of a social event and general party mood. The Panel noted that the Code stated that the impression created by the arrangements for any meeting must always be kept in mind. The Panel considered that the hospitality had been excessive and in that regard high standards had not been maintained. The Panel further considered that the arrangements were such as to bring discredit upon the industry. Breaches of the Code were ruled including a breach of Clause 2.

The Panel considered that Cephalon's representatives had not maintained a high standard of ethical conduct and in that regard it ruled a breach of the Code.

The Panel noted its rulings above and considered that Cephalon had not complied with all applicable codes. A breach of the Code was ruled.

With regard to compliance, the Panel noted that Cephalon had submitted that it had provided significant training to all staff in the past 2 years. There was no evidence to show that staff had not been trained on the Code. No breach of the Code was ruled.

The Code required companies to be responsible for the actions of their representatives if these were within the scope of their employment even if they were acting contrary to the instructions which they had been given. In that regard Cephalon had clearly taken responsibility for its representatives. No breach of the Code was ruled.

The Panel noted that the feedback document stated that at the Cephalon-sponsored symposium it was announced that sublingual use of Effentora had been approved in Europe. Cephalon had submitted that there was no evidence of this and that the licence for sublingual administration was not granted until three months later. Sublingual placement was referred to in the symposium but the Panel did not consider that this was necessarily unacceptable; the

legitimate exchange of medical and scientific information during the development of a medicine was not prohibited providing any such information or activity did not constitute promotion. Regardless of what was said in the symposium the Panel considered that the complaint was about the conduct of Cephalon's representatives because at the outset the complainant stated that he was surprised at some of the things that other hospital specialists got away with and how the managers encouraged it. The Panel considered that there was no evidence to show that the representatives had promoted Effentora in a manner inconsistent with the particulars listed in its summary of product characteristics. No breach of the Code was ruled.

The Panel noted that the feedback document stated that one of the delegates asked for clear differentiation between Effentora and Abstral and that this was 'a good opportunity to sell'. The complainant alleged that this implied that comparisons were made that were potentially misleading and which could not be substantiated. The Panel noted that there was no information as to what the representatives had said to the delegate in response to his request. On that basis the Panel ruled no breach of the Code.

An anonymous complainant writing as an 'Ex-Cephalon hospital specialist', complained about the hospitality offered by Cephalon (UK) Limited to delegates it had sponsored to attend a European pain congress in Lisbon in September 2009.

COMPLAINT

The complainant submitted that until recently he was a hospital specialist at Cephalon. He was sometimes surprised at some of the things that other hospital specialists got away with, and how the managers encouraged it.

The complainant provided a copy of a congress note from his time at Cephalon and submitted that some of the behaviour referred to in the document did not do him, other good representatives at the company or the industry any favours.

The complainant understood that the document was not approved as representative briefing material, which it should have been since it referred to a product and its indication; it bore no reference number or date. The complainant alleged a breach of Clauses 15.9 and 15.10.

The complainant further submitted that the meeting took place before the sublingual use of Effentora (fentanyl) had been approved and so this would have been promotion outside the licence, in breach of Clause 3.2.

The complainant noted that the document included a comment about differentiation between Effentora and ProStrakan's Abstral (fentanyl), 'so a good opportunity to sell'. The complainant stated that hospital specialists were only trained to refer

enquirers to the relevant summary of product characteristics (SPC) if asked about Abstral. Implied comparisons were made that were incapable of substantiation and potentially misleading in breach of Clauses 7.1 and 7.2.

The complainant was surprised to read 'We then took them out to the hotel until 2am and then [a named Cephalon employee] took them clubbing until 4am!'. This was surely inappropriate hospitality in breach of Clause 19.1, the representatives involved obviously failed to maintain high standards (Clause 15.2) and did not appear fully conversant with the requirements of the Code (Clause 16.1). The impression created brought discredit upon the industry in breach of Clause 2. The company had failed to comply with all applicable codes, laws and regulations, in breach of Clause 1.7.

Not only was such inappropriate hospitality extended once, but a second time according to the document: 'We then went to a few bars and to a club until 3am – a few good photos to prove it!!!!'. Here again was inappropriate hospitality in breach of Clause 19.1, the representatives concerned failed to maintain high standards (Clause 15.2) and did not appear fully conversant with the requirements of the Code (Clause 16.1) and the impression created brought discredit upon the industry in breach of Clause 2. The company had failed to comply with all applicable codes, laws and regulations in breach of Clause 1.7.

When writing to Cephalon, the Authority asked it to respond in relation to Clause 9.1 in addition to the clauses cited by the complainant.

RESPONSE

Cephalon noted that the complaint concerned arrangements for a meeting in Lisbon in September 2009. Despite having ample opportunity to raise concerns through company procedure, the complainant had waited 13 months to complain to the Authority. This made any subsequent investigation more difficult and meant that any necessary corrective actions that might have been identified could not be implemented. In this regard, the complainant had failed in his duty to both the company and the Code by not raising his concerns earlier.

Cephalon submitted that the feedback document provided by the complainant was a memorandum drafted and sent by an executive hospital specialist who attended the meeting. The company had been able to verify certain facts, in particular relating to expenses incurred at the meeting, but much of its understanding of the events relied on the memories of those who attended.

Arrangements for the meeting

Cephalon stated that it sponsored thirteen health professionals to attend the meeting and they were accompanied by a senior product manager (SPM), an

executive hospital specialist (EHS) and a hospital specialist (HS). However, the SPM returned to the UK for another meeting on the morning of Thursday, 10 September and so was only present for the evening of Wednesday, 9 September.

The delegates were sponsored on the basis of their experience in treating breakthrough cancer pain. The sponsorship consisted of economy flights (£188.28/head), registration to the congress (£7,000 for all attendees, registration costs varied depending on membership status), three nights' accommodation in a four star hotel in central Lisbon (£172/night) and subsistence.

Unfortunately, although the standard operating procedure (SOP) in place at the time required certification for such meetings and there were job bags for the international meetings arranged six months before and after this meeting, no job bag could be found for the meeting arrangements. Cephalon accepted that this omission was in breach of Clause 14.2 of the Code.

The delegates arrived on separate flights on Wednesday, 9 September and a number met for dinner in the hotel that evening. Although the company did not have a list of attendees at that meal, the recollection of the employees who were interviewed separately suggested that there were between seven and nine health professionals plus the three Cephalon employees (although both the EHS and SPM stated that they had arrived during the meal). Before dinner, HS and some of the delegates had a pre-dinner drink in the hotel bar. HS's expenses show that €44.20 [£39 approximately] was spent, which was in keeping with a single drink for each attendee. At the dinner, the recollection was that three bottles of wine and some bottles of water were ordered with the meal and that following the meal, some of the party returned to the bar for drinks and coffee. The expenses of HS showed costs in line with this (€153 [£134 approximately] for the wine/water and €85.50 [£75 approximately] for the post dinner drinks). The total cost of the meal and drinks was between €49 and €58 [£43 – £51 approximately] per person depending on whether the total was ten or twelve attendees. The approximate exchange rate in September 2009 was €1.14 = £1.

On Thursday, 10 September, as part of the Congress, a Cephalon sponsored symposium took place from 6.30 – 8.30pm and was followed by a dinner at a restaurant for all of the attendees. This was arranged and paid for by Cephalon's EU headquarters at a cost per head of €65 [£57 approximately]. The feedback stated that 'We took [the delegates] out to [a named] hotel until 2am and then [a named Cephalon employee] took them clubbing until 4am'. EHS submitted an expenses for four drinks at the hotel where some of the health professionals were staying, costing €24 [£21 approximately] at 12.37am and HS submitted a receipt for three drinks costing €20.50 [£18 approximately] at 1.11am, consistent with them returning to the hotel for a drink, but there was no evidence in either employee's expenses to

corroborate the second part of the statement regarding 'clubbing'.

On the Friday, there was a dinner held for the Cephalon UK sponsored group. This had been arranged and booked in advance by Cephalon UK. The meal cost €42 [£37 approximately] per person excluding drinks and the table was booked for twenty people, however only fifteen attended. The party walked from the hotel to the restaurant. The meal consisted of a tapas style menu and fourteen alcoholic drinks and two soft drinks were ordered. The service during the meal was very slow and at the end there was a discussion between the restaurant and EHS/HS because although only fifteen had eaten, the restaurant demanded full payment for twenty. This further delayed departure. The bill was paid at 1.13am and the party left shortly afterwards.

Both EHS and HS stated that the party left the restaurant at around 1.15am and was unable to find taxis back to the hotel. According to EHS, they decided to walk, but got lost. Further, HS had stated that the party then split up and a small group went into a bar to ask for a taxi (EHS submitted a receipt for a tea and an iced tea) and a larger group, including HS, continued to a bar. The two groups then met up again later. Based on receipts, it appeared that HS went to two different bars, the second after the two groups had joined again. HS submitted receipts from the two bars. The quantity of drinks purchased was in keeping with a single drink per person. From there, they both stated that the group went back to the hotel. Although two bars were visited, this did not appear to constitute 'clubbing' in the accepted interpretation of the word.

In retrospect, EHS accepted that her description of the hospitality as written in the congress note was not completely correct and that she had embellished the facts. HS's statement about the Friday night was consistent with both the version of EHS and was supported by the expense reports.

With regard to the photographs referred to in the congress note, most were of Lisbon and some of EHS and HS. There were seven pictures of the health professionals and a further nine of some fire eaters who they saw on the Friday night. The pictures that included four health professionals appeared to be taken inside a bar. They did not suggest that excess alcohol had been consumed and appeared to show the group sat together having a drink.

Based on the receipts and expenses submitted by HS and EHS, the level of hospitality provided to the health professionals on Wednesday, Thursday and during the meal on Friday appeared to be reasonable and acceptable. On leaving the restaurant on Friday night, EHS had a receipt for a bar where a cup of tea and an iced tea were ordered. This did not seem inappropriate or excessive. HS submitted two receipts from separate bars. At each location, six alcoholic drinks and two waters were ordered which was in keeping with one drink per attendee.

Cephalon accepted that this exceeded the level of hospitality that should be provided, contrary to its SOP and in breach of Clause 19.1, and that HS failed to maintain high standards in breach of Clauses 15.2 and 9.1 of the Code.

Cephalon stated that it undertook regular training on the Code and ensured that all staff were conversant with its requirements. The company did not accept the alleged breaches of Clause 1.7 or 16.1.

While the level of hospitality following the dinner on the Friday night was greater than that which should have been provided, EHS had claimed that the feedback document was embellished and exaggerated the hospitality provided. This was supported by the expenses claims that were processed for EHS and HS. No complaints had been received from health professionals or other companies; rather a written testimonial from a health professional who attended the meeting congratulated the company on the professionalism of the arrangements and EHS and HS. Cephalon therefore did not believe that this represented a breach of Clause 2.

Review process for the feedback document

Cephalon was deeply concerned about how the 'feedback' document was drafted, reviewed and the fact that it was distributed within the organisation given its content.

The company did not believe that all internal communication to representatives constituted 'briefing material' and although this document referred to Effentora and the indication, it represented a sharing of information about a meeting rather than briefing materials. As such, the company did not consider that it required certification and therefore did not accept the alleged breaches of Clause 15.9 and 15.10 of the Code.

Investigation had shown that the draft feedback was sent by EHS to HS for comments and was minimally changed. It was then sent to SPM, who 'approved' it and instructed that it should be sent to the sales team, the regional sales managers, the national sales manager, the medical director, the general manager. It was a serious error of judgement and inexcusable that SPM did not realise that the feedback document contained claims of activities that were in breach of Cephalon policy and the Code. Any of the recipients should have identified the serious nature of the activities listed and taken the appropriate actions. However, only one regional sales manager, the medical director and the national sales manager had any reaction. The primary concern appeared to have been the issue of whether Effentora had received the sublingual licence; only the medical director queried the reported hospitality.

One regional sales manager stated during the course of the investigation that he did not read the document. However, once it became apparent that the document had not been fully approved he asked

the medical director if the document should be withdrawn but received no reply. The regional sales manager also emailed SPM to ask whether the sublingual licence for Effentora had been granted. This prompted a corrective email to the sales team stating that Effentora was not licensed for sublingual use and that it must not be promoted. Any question that the team received on this matter had to be sent to medical information. The regional sales manager did not question the hospitality and related activities described in the document.

The national sales manager stated that he twice discussed his concerns about the content of the feedback document with the medical director who reassured him that he was taking action.

The medical director, who had subsequently left Cephalon, initially emailed one of the regional sales managers to ask if the feedback document had been sent out to anyone else, and stated that it would need head office approval before circulation. The medical director also stated that the feedback document was a 'great initiative', but did not raise any concern about the content. Nearly six hours later he emailed the national sales manager, the general manager and SPM to express his concerns over some of the comments made and state that the company should be 'careful since this document would clearly be seen as implying inappropriate activities if it were to reach the PMCPA'. The medical director did not suggest that any action should be taken, or an investigation initiated; he merely stated that 'obviously we're doing things to improve understanding of the Code and compliance. Any further suggestions?' The general manager could not recall the email, or taking any action having received it, and there was certainly no written reaction from him or the other recipients. It appeared, from discussions with the individuals involved and the review of email communication, as well as the general manager's own recollection of the matter, that the medical director took no further action in response to this matter. He had, however, emailed the feedback document to his personal email address immediately after his email in which he had expressed his concerns.

Although the general manager was also copied on the email distributing the feedback, he could not remember reading it. Certainly there was no email from him about the subject following the distribution. He also could not remember the level of hospitality ever being raised as an issue by the medical director or any of his team. When he saw the complaint, he was shocked by the claims and if he had known about this previously, he was certain that he would have immediately initiated an investigation and further actions as appropriate. However, as general manager, he accepted full responsibility for the actions of his team.

Cephalon UK had made significant progress in driving compliance as a core value and had provided significant training to all staff in the past two years. New SOPs had been implemented, including a new

meetings and hospitality SOP. Although this programme had been affected by the turnover in staff, particularly in the medical team, every member of staff recognised the importance of compliance and strove to achieve this.

Mention of the sublingual licence for Effentora at the Cephalon symposium

The Cephalon symposium at the Lisbon meeting was held on Thursday, 10 September from 6.30 – 8.30pm and Cephalon provided copies of the presentation entitled 'New Drug Delivery Technology Applied to Fentanyl: The Pharmacodynamics and Pharmacokinetics of Effentora' delivered by a senior company scientist. Data was presented comparing buccal vs sublingual placement of the tablets. This showed that the sublingual route was at least as good as the buccal route and this data formed the evidence for the application for sublingual use. Aside from the feedback document, Cephalon was not aware of any evidence that it was stated during the symposium that Effentora was now licensed for sublingual use in EU. Indeed, the licence for sublingual administration was not granted until December 2009.

As soon as the feedback document was circulated, as described above, it was identified that the licence for sublingual administration of Effentora had not been granted. Consequently the field force was reminded that any discussion about sublingual administration would be off-label and that any enquiry on this should be sent to medical information. Cephalon did not believe that there was any evidence of promotion of sublingual Effentora and therefore no breach of Clause 3.2.

Cephalon submitted that the allegation that the statement in the feedback 'there is a comment about differentiation between Effentora and Abstral "so a good opportunity to sell"' implied that misleading claims were then made was spurious and unsubstantiated and as such there could be no breach of Clauses 7.1 or 7.2.

Summary

The events in Lisbon in September 2009 demonstrated an error of judgement of HS, who was no longer with the company. In failing to maintain the high standard expected of him, he let himself and the company down and his actions were in breach of Clauses 9.1 and 15.2.

A review of expenses for all attendees at international meetings in the past year showed that all were in line with Cephalon's policy of hospitality which suggested that there was a high level of compliance in this area within the company generally.

EHS who wrote the feedback document had subsequently stated that the claims about 'going clubbing' were exaggerated and false. In addition, the failure by SPM to properly review the feedback

note before it was circulated was inexcusable. Both staff members were currently undergoing disciplinary action.

The failure to take corrective action when the 'feedback' was sent to a variety of managers was also unacceptable and was the subject of internal review and possible disciplinary action. This represented a failure to maintain high standards and a breach of Clause 9.1.

Cephalon also submitted that the failure to certify the arrangements for the meeting was in breach of Clause 14.2.

Cephalon denied breaches of Clauses 1.7, 3.2, 7.1, 7.2, 15.9, 15.10 or 16.1 as alleged by the complainant.

The facts of this case showed failings with regard to the level of hospitality provided to health professionals. However, Cephalon believed that the description in the feedback document of the actual hospitality provided was exaggerated, and it did not believe that the actual hospitality provided brought the industry into disrepute. There had been no complaints about Cephalon's activities at this meeting from other companies, or from health professionals. In fact, the company received a note of thanks from a physician in the sponsored group. Accordingly, Cephalon did not believe that this warranted a breach of Clause 2.

PANEL RULING

The Panel noted that the complainant was anonymous and uncontactable and that, as set out in the introduction to the Constitution and Procedure, complainants had the burden of proving their complaint on the balance of probabilities. Anonymous complaints were accepted and like all complaints were judged on the evidence provided by the parties.

The Panel noted that the complaint had been prompted by an internal feedback document detailing the aspects of the EFIC pain congress in Lisbon to which Cephalon had sponsored thirteen health professionals. The document made much of the hospitality provided to customers with phrases such as 'Dinner was fantastic', 'great night again', 'took them clubbing' and 'we then went to a few bars and to a club until 3am – a few good photos to prove it!!!'. The document concluded with 'All the customers were really looked after and spoke positively about Effentora – lets make sure they start Rxing now!'. The Panel noted that the feedback document had been distributed within Cephalon including to sales teams. The Panel considered that recipients would read the document and assume that it represented accepted practice with regard to hospitality. The Panel considered that the feedback document was, in effect, briefing material which advocated a course of action which would be likely to lead to a breach of the Code. A breach of Clause 15.9 was ruled.

The Panel considered that the impression given by

the feedback document of a general party atmosphere, recorded on camera, was wholly unacceptable. In that regard the Panel considered that high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel further considered that the references to the hospitality provided were such as to bring discredit upon the industry. A breach of Clause 2 was ruled.

The receipts from the various restaurants visited showed that on Wednesday evening a total bill of €588.70 (£516.40 approximately) was spent on food and drink (€306 on food and €282.70 on beverages) in the hotel where the delegates were staying. The approximate amount spent per head was thus £43 – £51 depending on whether 10 or 12 people had been present. On Thursday evening delegates attended a Cephalon-sponsored symposium and then had dinner in a restaurant at a cost of approximately £57/head. After the dinner two of the representatives returned to the hotel where some of the delegates were staying and expense receipts showed early morning bar bills which included the purchase of spirits and cocktails. On Friday evening the restaurant bill for 15 attendees was approximately £831 ie £55.40 per head. The restaurant had, however, demanded payment for the 20 covers booked and the bill appeared to show that the meal (excluding drinks) was to cost approximately £36.80 per head. On leaving the restaurant the group had walked back to the hotel, got lost, visited two bars (the receipts submitted were modest, approximately £30) watched fire-eaters and the feedback document implied that the evening finished at 3am.

Overall, the Panel considered that, on a cumulative basis, the hospitality provided went beyond subsistence. It appeared that the hospitality was not secondary to the main purpose of being in Lisbon ie to attend a European congress. That one of the Cephalon employees photographed the group added to the overall impression of a social event and general party mood. The Panel noted that the Code stated that the impression created by the arrangements for any meeting must always be kept in mind. The Panel considered that the hospitality had been excessive and a breach of Clause 19.1 was ruled. In that regard, high standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel further considered that the arrangements were such as to bring discredit upon the industry. A breach of Clause 2 was ruled.

The Panel considered that Cephalon's representatives had not maintained a high standard of ethical conduct and in that regard it ruled a breach of Clause 15.2.

With regard to compliance, the Panel noted that Cephalon had submitted that it had provided significant training to all staff in the past 2 years. There was no evidence to show that staff had not been

trained on the Code. No breach of Clause 16.1 was ruled.

The Panel noted its rulings above and considered that Cephalon had not complied with all applicable codes. A breach of Clause 1.7 was ruled.

The Panel noted that the complainant had alleged a breach of Clause 15.10. That clause, however, set out a principle of the Code ie that companies were responsible for the actions of their representatives if these were within the scope of their employment even if they were acting contrary to the instructions which they had been given. In that regard Cephalon had clearly taken responsibility for its representatives. No breach of Clause 15.10 was ruled.

The Panel noted that the feedback document stated that at the Cephalon-sponsored symposium it was announced that sublingual use of Effentora had been approved in Europe. Cephalon had submitted that there was no evidence of this and that the licence for sublingual administration was not granted until three months later on 10 December. Sublingual placement was referred to in the symposium but the Panel did not consider that this was necessarily unacceptable. The supplementary information to Clause 3 of the Code stated that the legitimate exchange of medical and scientific information during the development of a medicine was not prohibited providing any such information or activity did not constitute promotion which was prohibited under Clause 3 and any other clause. Regardless of what was said in the symposium the Panel considered that the complaint was about the conduct of Cephalon's representatives because at the outset the complainant stated that he was surprised at some of the things that other hospital specialists got away with and how the managers encouraged it. The Panel considered, however, that there was no evidence to show that the representatives had promoted Effentora in a manner inconsistent with the particulars listed in its summary of product characteristics. No breach of Clause 3.2 was ruled.

The Panel noted that the feedback document stated that one of the delegates asked for clear differentiation between Effentora and Abstral and that this was 'a good opportunity to sell'. The complainant alleged that this implied that comparisons were made that were potentially misleading and which could not be substantiated. The Panel noted that there was no information as to what the representatives had said to the delegate in response to his request. On that basis the Panel ruled no breach of Clauses 7.1 and 7.2.

Complaint received	5 October 2010
Case completed	1 December 2010