CASE AUTH/2232/5/09

ANONYMOUS FORMER REPRESENTATIVE v CEPHALON

Training of representatives promoting Effentora

An anonymous former representative from Cephalon complained about the company's training of its representatives with regard to the promotion of Effentora (fentanyl buccal tablet).

The complainant alleged that he had received the first and only face to face training on the Code at the Effentora launch meeting from 12-15 January 2009. Afterwards the complainant's line manager told staff not to change what they did but just to be more careful what information they put in the customer database and another manager suggested telephoning off-label targets to avoid being seen and thus reported by competitor companies.

At the launch meeting none of the training materials appeared to have been copy approved. The complainant had provided copies of some of the material at issue and queried whether they should also have the black triangle.

The complainant noted that staff were trained on an audio visual (AV) presentation which was intended for use with customers but were told that it had not been copy approved so there could be some changes in the final version.

As part of the Effentora Risk Management Plan, agreed with the European Medicines Evaluation Agency (EMEA), representatives had to give customers an Effentora Prescription Guide during the first Effentora call. The sales manager did not realise that staff needed to be trained on this document so they were trained on a copy that was not copy approved. None of the materials trained staff on when to use the Effentora Prescription Guide.

At the complainant's previous company staff were trained on written guidance on how much could be spent on speaker fees, lunches, dinners and other hospitality. The complainant had never been trained on this at Cephalon and nor had his colleagues. At the complainant's previous company staff were also trained on grants and donations, medical and educational goods and services and on how their expenses would be audited. The complainant was not aware that Cephalon had policies on these activities. It was difficult to see how senior managers thought that representatives could comply with the Code if they did not train them on Cephalon ABPI policies and procedures.

At the meeting in January, staff were trained mainly on promoting Cephalon's products in line with the summary of product characteristics (SPC). Staff were told that the targets lists were to be changed and more tightly controlled by head office in future. One of the other representatives had told the complainant that one of his children's hospital's targets was being deleted from the Actiq customer database because it was not licensed for use in children.

The detailed response from Cephalon is given below.

The Panel noted that a list of materials and certification status provided by Cephalon showed that some of material used to train the representatives at the Effentora launch meeting had not been certified including some of the materials specifically referred to by the complainant. The complainant had referred to an AV presentation. The Panel noted Cephalon's submission that an AV presentation had been presented at the meeting as a concept before final sign off. The Panel queried whether concept material should be used at a product launch/training meeting for representatives. In any event it was likely to be viewed as briefing material and should have been certified. Given that uncertified materials were used breaches of the Code were ruled as acknowledged by Cephalon. It was unclear as to whether the Effentora Script Detail Aid as referred to by the complainant had been certified before the meeting. Information provided by Cephalon in response to a request for a comprehensive list of materials and presentations used at the Effentora launch meeting showed that several items were certified after the event. The Panel agreed with Cephalon that the meeting agenda, as referred to by the complainant, did not need to be certified and no breach of the Code was ruled in that regard.

The Panel considered that the failure to certify much of the representatives' training material before it was used was unacceptable. The Panel noted Cephalon's submission that the circumstances leading up to the launch meeting had been exceptional. Nonetheless high standards had not been maintained and a breach of the Code was ruled.

The Panel considered that it was good practice to include the inverted black triangle on representatives' training materials. However, there was no evidence that the materials used at the training meeting had been used with health professionals and thus no breach of the Code was ruled.

The Panel noted Cephalon's submission that the representatives had been trained on the Effentora

Prescribing Guide and thus no breach of the Code was ruled.

The Panel noted that Cephalon had issued guidance on the allowable costs for meetings and other activities etc in addition to six standard operating procedures (SOPs). The guidance document was not dated.

Training was provided on the 2008 Code although the Panel queried why this was not completed until November of that year; the 2008 Code came into operation on 1 July with a three month grace period for newly introduced requirements. Materials relating to the Code were provided for representatives to read. The Panel noted that no training had been provided on medical and educational goods and services; an SOP was being produced. It appeared that Cephalon asked staff to read various documents and policies rather than providing structured training. A Code compliance project was ongoing with the aim of establishing policies and procedures to ensure ongoing compliance with the Code. The Panel was concerned about the arrangements for training the representatives. No evidence was provided documenting the training each representative received nor was documentation supplied with regard to phamacovigilance training.

Overall the Panel considered that although some training had been provided there was a need for more focused and validated training. Thus the Panel ruled breaches of the Code.

A senior employee (the general manager) had been appointed as the person responsible for ensuring Code compliance and so no breach was ruled. The Panel did not consider, on the material before it, that Cephalon had failed to adequately train its representatives such that they did not have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines they promoted. Nor was there information to show that representatives had not maintained a high standard of ethical conduct. No breaches of the Code were ruled.

The Panel noted that no evidence had been provided by the complainant to show that the alleged failure to train representatives on the company policies for hospitality, speaker fees, grants and donations had resulted in breaches of the Code. Thus the Panel ruled no breach of the Code. Such guidance was not necessarily regarded as briefing material and thus no breach of the Code was ruled.

The Panel considered that the inadequacy of the training arrangements at Cephalon meant that high standards had not been maintained and a breach of the Code was ruled.

Overall the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2.

With regard to the alleged promotion of unlicensed indications the Panel considered it was very important that representatives were given clear instructions regarding potential audiences. It was of concern that the complainant alleged that a manager suggested telephoning off-label targets so that 'the competitor company's representatives would not see Cephalon's representatives visiting them and report them'. The Panel noted Cephalon's explanation that health professionals at children's hospitals could work across several units – including adult units. Cephalon denied there was a policy to promote the use of Actiq in children. Although the Panel was concerned about the arrangements, in particular the lack of clear instructions to representatives, it did not consider that the complainant had proved their complaint on the balance of probabilities and thus no breach of the Code, including Clause 2 was ruled.

An anonymous former representative from Cephalon complained about the company's training of its representatives with regard to the promotion of Effentora (fentanyl buccal tablet) an opiod analgesic..

COMPLAINT

The complainant alleged that he had received the first and only face to face training on the Code at the Effentora launch meeting (12-15 January 2009). Afterwards the complainant's line manager told staff not to change what they did but just to be more careful what information they put in the TEAMS database [customer-relationship management database] and another manager suggested telephoning off-label targets so that the competitor company's representatives would not see Cephalon's representatives visiting them and report them.

The complainant alleged that none of the training materials used at the launch meeting had job bag numbers or a date of preparation which meant that they had not been copy approved (breaches of Clauses 9.1, 15.9 and 14.1). The complainant had provided some examples as proof of this:

- Training agenda for 13 and 14 January 2009.
- Effentora Script Detail Aid.
- Effentora BTcP [breakthrough cancer pain] and Treatment Strategy slide set.
- Practice detail role plays.

The complainant queried whether these materials should also have the black triangle (breach of Clause 4.11).

The complainant noted that staff were trained on an audio visual (AV) presentation intended for use with customers but were told that it had not been copy approved so there could be some changes in the final version (breach of Clause 14.1).

As part of the Effentora Risk Management Plan,

agreed with the European Medicines Evaluation Agency (EMEA), staff were told that all the representatives had to give customers an Effentora Prescription Guide during the first Effentora call. The Effentora sales manager did not realise that staff needed to be trained on this document so they were trained on a copy that was also not copy approved. None of the Effentora training materials trained staff on when to use the Effentora Prescription Guide, for example the practice detail role plays did not mention discussion of the Effentora Prescription Guide (breaches of Clauses 16.2, 7.10, 9.1, 14.1 and 15.9).

The complainant submitted that at his previous company staff were trained on written guidance on how much could be spent on speaker fees, lunches, dinners and other hospitality. The complainant had never been trained on this at Cephalon and nor had his colleagues (breaches of Clauses 19.1, 16.1, 15.2, 15.9 and 9.1). At the complainant's previous company staff were also trained on grants and donations, medical and educational goods and services and on how their expenses would be audited. The complainant was not aware that Cephalon had policies on these activities at all. In fact the complainant was not trained on any Cephalon ABPI Code policies (breaches of Clauses 9.1, 15.2, 15.9, 16.1, 19.1 and 2). The complainant doubted if Cephalon had policies and procedures or evidence of training staff on them (breach of Clause 15.9). It was difficult to see how senior managers thought that representatives could comply with the Code if they did not train them on Cephalon ABPI policies and procedures (breaches of Clauses 9.1, 15.1, 15.2, 15.9, 16.1, 16.2, 1.7, 1.8 and 2).

At the ABPI Code training in January, staff were trained mainly on promoting Cephalon's products in line with the summary of product characteristics (SPC) (Clause 3.2). Staff were told that the targets lists were to be changed and more tightly controlled in future. One of the other representatives had told the complainant that one of his children's hospital's targets was being deleted from TEAMS for Actiq because it was not licensed for use in children (breaches of Clauses 3.2, 9.1 and 2).

Overall the complainant alleged that Cephalon did not take the Code as seriously as other companies that he had worked for and seemed to get away with putting less effort and resources into it. This did not seem fair or ethical when the same standards should be applied.

The complainant noted that he had not felt able to raise these issues when working at Cephalon.

RESPONSE

Cephalon noted that the complaint was from an anonymous former representative; it was unfortunate that such matters had been brought to the Authority's attention without recourse by that employee during their employment.

1 Code training and alleged line manager statements

Cephalon disputed the allegation that any line manager had directed representatives to behave in a manner outside of the requirements of the Code and company policies. No specific clauses of the Code were cited in regard to this aspect of the complaint, so Cephalon only responded to the information provided.

The complainant provided no further information as to what behavior need not change or the nature of the caution over database entries.

With respect to the allegation of telephoning off-label targets, no briefings would direct representatives to take actions that would compromise compliance with the Code. The training delivered at the launch meeting reinforced the importance of promoting within the licence.

In summary, Cephalon refuted the allegation as it knew of no evidence to support it.

2 Effentora launch meeting materials

Cephalon noted that it was alleged that none of the training materials used at the launch meeting had job bag numbers or a date of preparation, implying that they had not been copy approved. A number of materials were submitted as evidence. However Cephalon submitted that the key training manuals on Effentora were certified and materials could be supplied to support this point.

The alleged breach of Clause 9.1 was not applicable to such training materials, as the high standards relevant to this clause related to materials used with health professionals ie promotional.

Cephalon accepted the alleged breaches of Clauses 15.9 and 14.1, relating to the failure to certify materials, and specifically briefing materials. However, the agenda submitted as proof did not contain information that otherwise required certification, hence there was no code number, although it was dated.

Cephalon submitted that, with reference to the alleged breach of Clause 4.11, the requirement to include a black triangle only applied to promotional materials. As training or briefing materials, this clause was not applicable, although Cephalon accepted that it was good practice to include this on internal material.

Cephalon submitted that an AV presentation was presented as a concept, prior to being finally certified, and was not given to representatives. Cephalon refuted the allegation that such use constituted a breach of Clause 14.1.

Cephalon submitted that its representatives were trained on pharmacovigilance responsibilities

during their initial training, and at least annually. A verbal brief was provided to the representatives regarding use of the Prescription Guide during the role play activities. During the initial Effentora product training (17-21 November 2008 and 1-5 December 2008), presentations were made on the Risk Management Plan, at which time the Prescription Guide was referred to verbally and the requirements to provide during a detail. As such, Cephalon refuted the alleged breaches of Clauses 16.2, 7.10, 9.1, 14.1 and 15.9. The certified Prescription Guide was available for use by representatives following the launch meeting and its use within calls had been tracked since launch.

In response to a request for further information Cephalon provided a list of material and presentations used at the launch meeting together with details as to their certification status. Guidance regarding costs of meetings was also provided and this included guidance for honoraria. The company was in the process of producing a standard operating procedure (SOP) on the provision of medical and educational goods and services and grants and donations.

Cephalon submitted that it planned to update all documentation and training relating to requirements of the Code. The circumstances leading up to the internal launch meeting were exceptional, with serious, long-term illness of the responsible product manager. However, Cephalon had already identified the need to review the current policies and procedures and this was ongoing.

3 Cephalon policies and training on the Code

Cephalon submitted that during November 2008 all sales representatives completed the Code 2008 update module available via Wellards. A project was implemented for 2009 to address numerous aspects of policies, procedures and training within Cephalon. Currently, there were SOPs for the following:

- Approvals and certification of promotional material (SOP-0004710)
- Withdrawal of promotional material (SOP-0004713)
- Handling of medical information enquiries (SOP-0004714)
- Meetings approval (SOP-0004718)
- Provision of information regarding unlicenced use (SOP-0004719)
- Direct healthcare professional communications (SOP-0004720)

Cephalon submitted that the Code compliance project was an all-encompassing review and implementation to establish the policies and procedures required to ensure ongoing compliance with the Code and other applicable requirements.

The complainant alleged that no training was provided on meetings and hospitality. Cephalon submitted that all employees could access current policies and procedures, where such a policy existed, on the company intranet. As such, Cephalon refuted the alleged breach of Clause 19.1.

Cephalon's practice was to employ representatives who were familiar with the Code and who had successfully completed the ABPI Representatives Examination.

Cephalon submitted that in addition to completing the Wellards training, there was a training session at the launch meeting which was further evidence of training focused on the requirements of the Code. 'The Code in Practice' and the 'The Code in the Field' books were given to appropriate personnel in February 2009. Therefore, Cephalon refuted the allegation that personnel were not conversant with the requirements of the Code (Clause 16.1).

Cephalon submitted that with regard to the alleged breach of Clause 15.2 that representatives had not maintained high standards, there was nothing in the complaint that identified specific representative activity for this to be considered relevant or for a response to be produced.

Cephalon submitted that the alleged breach of Clause 15.9 related to there being no detailed briefing materials. Again, there was no specific allegation as to what briefing materials. Effentora training manuals had been reviewed and certified on 11 September 2008.

Cephalon submitted that the alleged breach of Clause 9.1 was not applicable here, as the high standards relevant to this clause related to promotional activities and materials used with health professionals. The complainant had made no specific allegation relating to promotional activity.

Cephalon refuted that the alleged breach of Clause 15.1 regarding lack of adequate scientific training on promoted medicines. The training manuals were certified for briefing purposes and two separate training modules were performed for the two business units (17-21 November 2008 and 1-5 December 2008).

Cephalon reiterated that its representatives were trained on pharmacovigilance responsibilities during their initial training, and at least annually. During the initial Effentora product training (17-21 November 2008 and 1-5 December 2008), presentations were made on the Risk Management Plan. As such, Cephalon refuted the alleged breaches of Clause 16.2.

Cephalon refuted that the alleged breach of Clause 1.7, not complying with all applicable codes, laws and regulations. No specific allegations were made. To Cephalon's knowledge it fulfilled these obligations by the explicit expectation that all

personnel complied with the Code.

Cephalon denied the allegation that it had not appointed a senior employee responsible for ensuring the company met the requirements of the Code; the general manager assumed this obligation. Therefore, Cephalon refuted the alleged breach of Clause 1.8.

Cephalon noted that although the complainant had alleged a breach of Clause 2, bringing discredit to, and reducing confidence in the industry, no allegations or examples submitted constituted such a breach.

4 Children's hospital targets

Cephalon submitted that the complainant referred to Code training during the January meeting, and being trained on promoting products in line with the SPC, correctly referring to Clause 3.2. This was a specific aspect of the training session.

The complainant referred to anecdotal information that a target in a children's hospital had been deleted from the TEAMS database because Actiq did not have a licence for children. The alleged breaches of Clauses 3.2, 9.1 and 2 were refuted. In the absence of details relating to a specific health professional, hospital or representative then Cephalon had insufficient information to investigate this matter further.

In response to a request for further information about whether health professionals at children's hospitals had been on target lists for Actiq, Cephalon stated that its customer targeting was a dynamic process with periodic list revisions. In line with data protection legislation it did not hold information that was no longer relevant. It was therefore not possible to give an accurate answer covering all of 2008. However, based on the last two list revisions kept on file, covering the second half of 2008, there were six health professionals with an Actiq target flag co-located in children's hospitals or children's units during 2008. Two of these were flagged as target customers and the remainder as support personnel (such as nursing staff). Two of the six health professionals had not been contacted by Cephalon as far back as records existed. Five of the six health professionals had palliative medicine listed as a prime speciality and would be responsible for adult patients.

The database of health professionals was compiled by a third party. Health professionals were given one address within the database, although they could work across several units (eg in both adult and children's units as palliative medicine specialists). These health professionals could thus be seen at an alternative address (eg the adult unit), although the call record defaulted to the primary address which might be a children's unit. There had been no policy to promote the use of Actiq in children.

PANEL RULING

The Panel noted that Clause 15.9 required that representatives' briefing material was produced and certified. Briefing material consisted both of the training material about the product and the instructions as to how it should be promoted. The requirement to certify applied to printed briefing material and to the transcripts used in presentations to representatives. The Panel noted that a list of materials and certification status provided by Cephalon showed that when the Effentora launch meeting took place (12-15 January) some of material used to train the representatives had not been certified. Of the materials specifically referred to by the complainant the Effentora BTcP and Treatment Strategy slide set, the role play materials and the Effentora Prescribing Guide had not been certified. The complainant had also referred to an AV presentation. The Panel noted Cephalon's submission that an AV presentation had been presented at the meeting as a concept before final sign off. The Panel queried whether concept material should be used at a product launch/training meeting for representatives. In any event it was likely to be viewed as briefing material and should have been certified. Given that uncertified materials were used a breach of Clauses 14.1 and 15.9 was ruled as acknowledged by Cephalon. It was unclear as to whether the Effentora Script Detail Aid had been certified before the meeting. Information provided by Cephalon in response to a request for a comprehensive list of materials and presentations used at the Effentora launch meeting showed that several items were certified after the event. The Panel agreed with Cephalon that the meeting agenda did not need to be certified and no breach of Clauses 14.1 and 15.9 was ruled in that regard.

The Panel considered that the requirement of Clause 9.1 to maintain high standards applied to all activities covered by the Code – it was not limited to promotional activities as submitted by Cephalon. The Panel considered that the failure to certify much of the representatives' training material before it was used was unacceptable. The Panel noted Cephalon's submission that the circumstances leading up to the launch meeting had been exceptional. Nonetheless high standards had not been maintained and a breach of Clause 9.1 was ruled.

As acknowledged by Cephalon the Panel considered that it was good practice to include the inverted black triangle on representatives' training materials. Of the materials specifically referred to in this regard by the complainant the Effentora Script Detail Aid and the practice detail role plays did not incorporate the black triangle symbol. However, the Panel noted that Clause 4.11 only required a black triangle to be included on promotional material. There was no evidence that the materials used at the training meeting had been used with health professionals and thus no breach of Clause 4.11 of the Code was ruled.

The Panel noted Cephalon's submission that the representatives had been trained on the Effentora Prescribing Guide and thus no breach of Clauses 7.10 and 16.2 was ruled.

The Panel noted that Cephalon had issued guidance on the allowable costs for meetings and other activities etc in addition to the six SOPs. The guidance document was not dated.

Training was provided on the 2008 Code via Wellards although the Panel queried why this was not completed until November of that year; the 2008 Code came into operation on 1 July with a three month grace period for newly introduced requirements. Materials relating to the Code were provided for representatives to read. The Panel noted that no training had been provided on medical and educational goods and services; an SOP was being produced. It appeared that Cephalon asked staff to read various documents and policies rather than providing structured training. A Code compliance project was ongoing with the aim of establishing policies and procedures required to ensure ongoing compliance with the Code. The Panel was concerned about the arrangements for training the representatives. No evidence was provided documenting the training each representative received nor was documentation supplied with regard to phamacovigilance training.

Overall the Panel considered that although some training had been provided there was a need for more focused and validated training. Thus the Panel ruled breaches of Clauses 16.1 and 16.2 of the Code.

Cephalon had not complied with the Code and thus a breach of Clause 1.7 was ruled. As required by Clause 1.8 a senior employee (the general manager) had been appointed as the person responsible for ensuring Code compliance and so no breach of that clause was ruled.

The Panel did not consider, on the material before it, that Cephalon had failed to adequately train its representatives such that they did not have sufficient scientific knowledge to enable them to provide full and accurate information about the medicines they promoted. Nor was there information to show that representatives had not maintained a high standard of ethical conduct. No breach of Clauses 15.1 and 15.2 was ruled.

The Panel noted that no evidence had been provided by the complainant to show that the alleged failure to train representatives on the company policies for hospitality, speaker fees, grants and donations had resulted in breaches of the Code. Thus the Panel ruled no breach of Clauses 19.1 and 15.2. Such guidance was not necessarily regarded as briefing material and thus no breach of Clause 15.9 was ruled.

The Panel considered that the inadequacy of the training arrangements at Cephalon meant that high standards had not been maintained and a breach of Clause 9.1 of the Code was ruled.

Overall the Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code which was used as a sign of particular censure.

With regard to the alleged promotion of unlicensed indications the Panel considered it was very important that representatives were given clear instructions regarding potential audiences. It was of concern that the complainant alleged that a manager suggested telephoning off-label targets so that 'the competitor company's representatives would not see Cephalon's representatives visiting them and report them'. The Panel noted Cephalon's explanation that health professionals at children's hospitals could work across several units – including adult units. Cephalon denied there was a policy of promoting use of Actiq in children. Although the Panel was concerned about the arrangements, in particular the lack of clear instructions to representatives, it did not consider that the complainant had proved their complaint on the balance of probabilities and thus no breach of Clauses 3.2, 9.1 and consequently Clause 2 were ruled.

Complaint received **22 May 2009**

Case completed **6 July 2009**