

# PRIMARY CARE TRUST HEAD OF PRESCRIBING v ALTANA PHARMA

## Conduct of representative

The head of prescribing at a primary care trust (PCT) complained about the promotion of Alvesco (ciclesonide) by representatives from Altana. The complainant stated that he and a GP colleague met two of the representatives to discuss the evidence, cost and place in therapy of Alvesco. The representatives intimated that Altana had placed its product after beclometasone dipropionate (BDP), but as an alternative to other steroids and to step 3 of the British Thoracic Society (BTS) asthma guidelines. One of the representatives repeatedly asked the complainant to endorse this placement of the product in therapy. This request was repeatedly refused. The complainant stated that the PCT would not, and could not endorse what was a significant deviation from the BTS asthma guidelines. The complainant told the representatives that he could not stop them promoting Alvesco in this way but made it clear that he most certainly would not endorse this place for the product.

The complainant later learnt that another Altana representative had told a practice nurse that the complainant had endorsed the product in the position as described above. The complainant alleged that this was in breach of the Code and morally and ethically objectionable. He was appalled that having repeatedly stated, very clearly, that he would not endorse individual products in this way, Altana had ignored this and misquoted him in order to gain product endorsement.

The complainant alleged that the information Altana had used, and attributed to him, was inaccurate and misleading. In addition, the company could not substantiate the claims.

Commenting on Altana's response to the complaint, the complainant stated that he had placed Alvesco at step 2 of the BTS guidelines only in patients who got oral side effects from the first line choice, BDP. Furthermore, that Alvesco should not be used in patients who were uncontrolled at step 2, before moving to step 3, as it was not his, or his colleague's, place to amend the BTS guidelines for local use.

The Panel considered that it was beholden upon representatives to be abundantly clear when using the names of health professionals to endorse a promotional message. The circumstances were complicated in that the complainant had met two Altana representatives to discuss Alvesco and its place in therapy. As a result of that discussion the representatives had presumably briefed another Altana representative who had in turn discussed the outcome of the meeting, at which he was not present, with a practice nurse. It was a remark made to the practice nurse which had prompted the complaint.

The complaint focussed on when Alvesco should be used within the BTS guidelines. Step 2 of the guidelines involved the 'as required' use of a short-acting B<sub>2</sub> agonist plus the regular use of inhaled corticosteroids, BDP or equivalent. If asthma worsened then patients progressed to step 3 and a long-acting B<sub>2</sub> agonist was added to the existing corticosteroid therapy. The complainant had given permission for representatives to state that they had

discussed the use of Alvesco with him but he had not endorsed their placement of Alvesco in therapy, ie as an alternative to BDP in patients uncontrolled at step 2 of the BTS guidelines instead of progressing to step 3. In the complainant's view, Alvesco should only be used at step 2 of the BTS guidelines in the small number of patients who were uncontrolled with BDP therapy (the PCT's first choice inhaled steroid) because compliance was compromised by oral side effects.

Altana's response stated that the representative who had spoken to the practice nurse had understood that the complainant had endorsed the use of Alvesco once BDP had not been successful and before resorting to combination therapy. This was not so.

The promotional literature for Alvesco placed the product as an alternative to BDP at step 2 of the BTS guidelines in patients uncontrolled on BDP without any reference to poor compliance. The BTS guidelines, however, did not indicate that patients uncontrolled at step 2 on one inhaled steroid should try an alternative inhaled steroid; patients in whom asthma was uncontrolled should progress to step 3. The Panel noted that Altana had referred to the 'tight confines of the agreement with the complainant'. In the Panel's view, however, the promotional literature positioned Alvesco for a wide range of patients.

The Panel considered it unlikely that the complainant, head of prescribing at a PCT, would endorse a course of action which was not referred to in the BTS guidelines and this was supported by the complainant's comments. The complainant's name had been used, with his permission, by a representative during the course of promoting Alvesco. The promotional literature positioned Alvesco in a way which was not referred to in the BTS guidelines, ie as an alternative for use in any patient uncontrolled on BDP. The Panel thus considered that, on the balance of probability, the practice nurse had been led to believe that the complainant endorsed Altana's positioning of Alvesco which was not so. The Panel considered that the representatives had failed to maintain a high standard of ethical conduct and had failed to comply with all relevant requirements of the Code. Formal permission had not been obtained in relation to the quotation used by the representative with the practice nurse, ie the misquotation. Breaches of the Code were ruled. The Panel did not consider that the circumstances warranted a ruling of a breach of Clause 2 of the Code.

Upon appeal by Altana, the Appeal Board noted that one of the representatives who had met with the complainant had emailed an account of that meeting

to, *inter alia*, the representative who had subsequently visited the practice nurse. The Appeal Board considered that the email showed that the representative had had to work extremely hard to get any agreement out of the complainant. Agreements gained in such circumstances should be treated with caution. The Appeal Board considered that following such a protracted discussion the representative should have written to the complainant so that both parties could confirm their understanding of what had been agreed. It was beholden upon representatives to be abundantly clear when using the names of health professionals to endorse a promotional message. In circumstances where companies sought to gain the endorsement of public bodies, ie PCTs and the like, for their products, the Appeal Board considered that they would be well advised to confirm formal agreement before making such endorsement known.

On the evidence before it, the Appeal Board was satisfied on the balance of probabilities that the complainant's views about the positioning of Alvesco had been misrepresented. The Appeal Board upheld the Panel's rulings of breaches of the Code.

The head of prescribing at a primary care trust (PCT) complained about the promotion of Alvesco (ciclesonide) by representatives from Altana Pharma Limited.

## COMPLAINT

The complainant stated that he and a GP colleague met two representatives to discuss the evidence, cost and place in therapy of Alvesco. The representatives intimated that Altana had placed its product after beclometasone dipropionate (BDP), but as an alternative to other steroids and to step 3 of the British Thoracic Society (BTS) asthma guidelines. During the meeting one of the representatives repeatedly asked for a written endorsement for the product and this position in therapy from the PCT. This request was repeatedly refused. Furthermore, the complainant had stated that the PCT would not, and could not endorse this position for any product as it was a significant deviation from the BTS asthma guidelines.

The complainant was asked how he would react if representatives promoted Alvesco in this way locally. The complainant told the representatives that he could not stop them and again made it clear that he most certainly would not endorse this place for the product.

To his consternation, the complainant learnt on 9 June that a GP representative from Altana, had told a practice nurse that the complainant had endorsed the product in the position as described above. The complainant alleged that this was in breach of the Code and morally and ethically objectionable. He was appalled that having repeatedly stated, very clearly, that he would not endorse individual products in this way, Altana had ignored this and misquoted him in order to gain product endorsement.

The complainant alleged that the information Altana had used, and attributed to him, was inaccurate and

misleading. In addition, the company could not substantiate the claims. The complainant alleged breaches of Clauses 7.2, 7.4, 7.6 and 11.3 of the Code.

When writing to Altana, the Authority asked it to respond in relation to Clauses 2, 9.1 and 15.2, in addition to Clauses 7.2, 7.4, 7.6 and 11.3 cited by the complainant.

## RESPONSE

Altana explained that Alvesco was an inhaled corticosteroid for the treatment of persistent asthma in adults and adolescents (12 years and older). According to the BTS guidelines inhaled steroids were the most effective preventer medicine for achieving overall treatment goals. Step 2 of the guidelines involved the regular inhalation of a corticosteroid to reduce the frequency of asthma exacerbations (by decreasing lung inflammation) and the use of a short acting beta-2-agonist to relieve the symptoms of an asthma exacerbation (by dilating the small airways). Step 3 included the regular usage of a long-acting beta-2-agonist (to help maintaining airway dilatation) in addition to medication given at step 2 if asthma control was inadequate with step 2 therapy only.

Alvesco had clearly been marketed for use at step 2 which advised inhaled steroids as first choice preventer drug, it did not mention a particular inhaled steroid as first choice preventer drug. From a marketing perspective Altana positioned Alvesco after BDP and before combination inhalers. It should be considered as an alternative to other inhaled steroids in step 2 patients who were having symptoms of asthma despite step 2 therapy. Alvesco might be of considerable benefit to patients who had compliance problems due to oral pharyngeal side effects or complex treatment regimen with other inhaled steroids.

It was appropriate medical practice for a physician to consider changing a step 2 patient to Alvesco if the physician believed that the patient might benefit from the alternative characteristics of the product before exposing the patient to the additional medication of step 3 therapy. Clearly for patients with increasing asthma symptoms despite compliance at step 2 it would be inappropriate to remain at step 2 and they should be immediately commenced on the increased medical regimen of step 3. Determination of therapy was for the prescribing physician to decide on the basis of their clinical judgement.

The positioning of Alvesco was within the BTS guidelines and was supported by a large number of physicians and formulary inclusions. The briefing notes and sales materials showed that Alvesco was clearly positioned in step 2 therapy.

Altana submitted that this complaint hinged on the content of two meetings between Altana representatives and health professionals:

From the meeting report and notes of the first meeting (provided) and subsequent interviews with relevant employees, it was clear that the meeting with the complainant was productive and good-natured. It lasted an hour and a half and two of the outcomes that illustrated the mutually productive nature of the

meeting were that he agreed to see a representative again to discuss Protium and he brought up the subject of respiratory education and suggested that the representative contact a local respiratory nurse consultant.

The length of the meeting and the indisputable outcomes would be highly unlikely to have occurred if the meeting had been antagonistic or overtly confrontational.

Altana submitted that the meeting notes also clearly stated that:

1 The complainant agreed that provided that a GP had used BDP and then wanted to use Alvesco, he would be happy with the situation and would 'not come down on any practices doing so'.

2 The complainant was specifically asked if he would give his endorsement to using his name when seeing GPs and practice nurses and discussing Alvesco for use after BDP. He agreed.

3 The complainant agreed that patients who were poor compliers, those who had oral side effects, those fearful of inhaled corticosteroids and those who would benefit from the convenience of once daily therapy were all patients on whom he would be happy to see Alvesco used. (Patient profiles in sales materials.)

4 The complainant was not happy for Alvesco to be used as first line therapy ahead of BDP as it was against the formulary guideline and the BTS guidelines. (the complainant's statement about Alvesco not included as first line therapy ahead of BDP in the formulary guideline was correct but his statement about Alvesco in the BTS guidelines was incorrect. According to the BTS guidelines and the Alvesco summary of product characteristics (SPC), Alvesco was one of the inhaled steroids that could be prescribed as a first choice preventer in step 2 therapy).

5 Neither the complainant nor the GP were prepared to write a newsletter to support the use of Alvesco.

6 The complainant did not support any position other than Alvesco being used after BDP at step 2.

7 The complainant knew of inappropriate use of combination therapy locally at step 1 and step 2 which was outside the BTS guidelines for asthma management.

One of the representatives at the meeting agreed that the meeting report sent by the other representative accurately reflected the content and agreements from the meeting with the complainant. This representative was surprised by the complaint because the meeting was handled professionally and the positioning of Alvesco during the meeting was for step 2 therapy after BDP, which gained the complainant's endorsement and agreement for his name to be used in sales calls for this specific product usage.

The representative who sent the report recalled asking the complainant to write an endorsement for Alvesco but refuted the allegation that she 'repeatedly asked' as alleged in the complaint. She was surprised at the complaint as the meeting was 'good-humoured' and

she was confident that no issues relating to Alvesco were left unresolved.

Altana noted that the complainant alleged that an unnamed nurse informed him that a GP representative from Altana had told her that he endorsed Alvesco as an alternative to other steroids and to step 3 of the BTS Guidelines.

Altana submitted that it had no more information on this meeting. The company did not have the nurse's name and it was therefore impossible for it to be certain that it had obtained the correct electronic meeting notes that were created. Although there was a short list of meetings that this representative undertook with nurses in the area between 2 June and 9 June, Altana was not able to use the electronic record to give it highly relevant information, which would have helped create a more robust version of events.

However, on interview, the representative was extremely surprised to learn of the complaint, as he had not deviated from the agreed product messages or the communication from one of the representatives at the meeting with the complainant in any of the potential meetings from which the complaint arose. He was consistent with the primary care sales materials used (provided). For further clarity during the interview, he was asked to state his understanding of the Alvesco positioning that had been endorsed by the complainant; he responded in line with both the Altana Alvesco positioning and the positioning supported by the complainant – that Alvesco could be used once BDP had not been successful and before resorting to combination therapy.

Altana submitted that the behaviour of its representatives had been of the highest order, promoting a product in line with the marketing authorization, the BTS guidelines, current medical practice and within the tight confines of the agreement with the complainant to use his name in support for a specific product positioning. Therefore Altana did not consider that it had breached Clauses 2, 9.1, 11.3 or 15.2 of the Code.

The briefing notes and sales materials provided in its response unequivocally confirmed that Alvesco was positioned as step 2 therapy, in line with the BTS guidelines and current medical therapy. Whilst the complainant did not specifically cite any one particular piece of promotional material for censure Altana was certain that all of its materials were robust and complied with the Code. Therefore Altana did not consider that Clauses 7.2, 7.4 or 7.6 had been breached.

In summary, whilst Altana deeply regretted that a misunderstanding occurred during a meeting between its representative and a nurse it could not be held responsible given the high standards of both the promotional positioning by the representative and the promotional materials and the agreement with the complainant to use his name during the call to support the positioning of the product.

#### **FURTHER COMMENTS FROM THE COMPLAINANT**

The complainant stated that he and his colleague were astonished by Altana's notes of the meeting as this was certainly not their recollection of how the

meeting progressed and frankly they found it difficult to provide enough compelling information to allow a breach to be ruled. Nonetheless they would try to provide their account of the meeting, point out the inaccuracies as they saw them, in Altana's account of the meeting and provide, where possible, reason why their account might be a more acceptable version of events. Taking Altana's points in order:

1 Altana stated that the complainant would not reprimand any practice for using Alvesco provided it had used BDP first.

This was accurate. The PCT's formulary positioned BDP as the first choice inhaled steroid. Provided that clinicians followed the formulary the complainant was not concerned with product choice beyond the first line selection.

2 Altana stated that permission was given for names to be used when discussing Alvesco for use after BDP.

Indeed permission was given for the Altana representatives to state that they had met with the complainant and his colleague during promotional activity for Alvesco, however the placing of the product was not as described here (see later).

3 Altana stated that agreement was reached that Alvesco could be used in patients who were poor compliers, had oral side effects, who were fearful of steroids or who would benefit from a once daily product.

The complainant actually stated that he could not stop Altana marketing its product in this way despite the fact that he and his colleague disagreed with it. There was no evidence to support greater compliance with Alvesco compared to other steroids, it was still an inhaled steroid and once daily dosing had not been shown to improve outcomes over products with a greater frequency of administration. These factors made many of Altana's arguments irrelevant. The conversation therefore focussed upon oral side effects, which despite the complainant's concerns were, according to nursing colleagues, very rare. As such the complainant and his colleague stated that they would be happy with the product being used in the niche of patients for whom oral side effects might affect continued compliance but no more.

4 Altana stated that the complainant and his colleague were not happy to place Alvesco as first line steroid choice ahead of BDP.

This was accurate. The complainant and his colleague stated that using the STEP model (safety, tolerability, efficacy, price) to assess the place of Alvesco compared to treatment with BDP, Alvesco was a black triangle medicine and therefore safety could not be assured to the same extent as BDP. It was perhaps as well tolerated and efficacious from the trial data but was more expensive. Based on the current data therefore it must be placed after BDP.

Altana additionally stated that Alvesco was named at step 2 of the BTS guidelines.

This was not disputed, however it was not placed between step 2 and 3 (see later). Patients who were uncontrolled at step 2 of the BTS guidelines had therapy added, not steroid changed.

5 Altana stated that neither the complainant nor his colleague were prepared to write a newsletter in support of Alvesco.

This was accurate. The only question to be raised here though was if they had been happy placing Alvesco where Altana stated that they were, why then would they refuse to write this in a newsletter?

6 Altana stated that the complainant and his colleague did not support any position for Alvesco other than step 2 after BDP.

This statement was vague and perhaps open to interpretation. The complainant and his colleague stated at the meeting and reiterated above that they placed Alvesco at step 2 of the BTS guidelines for patients who were well controlled but suffered oral side effects that might affect continued compliance. This statement could also be interpreted to mean that Alvesco could be used after BDP at step 2 before moving to step 3. This interpretation was inaccurate. The role of the complainant and his colleague within the PCT was to advise clinicians on appropriate medicine choice, not to override nationally recognised guidelines for disease treatment. The complainant and his colleague most certainly would never suggest delaying stepping up any patient who was poorly controlled at the current step of the BTS guidelines and there was no reason not to step up using the guidelines unless control was poor.

7 Altana stated that the complainant and his colleague were aware of inappropriate use of combination products locally at step 1 and step 2.

This was partly accurate. The complainant and his colleague were aware of patients who were at step 1 or who were newly diagnosed being treated with combination products (step 3) without correctly progressing through the BTS management steps.

In summary the complainant stated that he and his colleague recalled that they placed Alvesco at step 2 of the BTS guidelines and suggested that it might be used only in patients who got oral side effects from the first line choice, BDP. Furthermore, they disagreed with Altana that Alvesco could be used in patients who were uncontrolled at step 2, before moving to step 3, as it was not their place to amend the BTS guidelines for local use.

Despite this placing of Alvesco it seemed obvious from Altana's response that information was relayed to the representatives that Alvesco had been endorsed by the complainant and his colleague as an alternative to other steroids and to step 3 of the BTS guidelines. It would be noted from the above that they most certainly did not place Alvesco as an alternative to step 3 and stated that it was an alternative to BDP at step 2 only where oral side effects were a problem.

The complainant and his colleague stated that to the best of their knowledge, the above represented a true account of the meeting.

## PANEL RULING

The Panel noted that the parties' accounts differed; it was difficult in such cases to know exactly what had transpired. A judgement had to be made on the

available evidence bearing in mind that extreme dissatisfaction was usually necessary on the part of an individual before he was moved to actually submit a complaint.

The Panel considered that it was beholden upon representatives to be abundantly clear when using the names of health professionals to endorse a promotional message. The circumstances were complicated in that the complainant had met two Altana representatives to discuss Alvesco and its place in therapy. As a result of that discussion the representatives had presumably briefed another Altana representative who had in turn discussed the outcome of the meeting, at which he was not present, with a practice nurse. It was a remark made to the practice nurse which had prompted the complaint.

The complaint focussed on when Alvesco should be used within the BTS guidelines. Step 2 of the guidelines involved the 'as required' use of a short-acting B<sub>2</sub> agonist plus the regular use of inhaled corticosteroids, BDP or equivalent. If asthma worsened then patients progressed to step 3 and a long-acting B<sub>2</sub> agonist was added to the existing corticosteroid therapy. The complainant had given permission for representatives to state that they had discussed the use of Alvesco with him but he had not endorsed their placement of Alvesco in therapy, ie as an alternative to BDP in patients uncontrolled at step 2 of the BTS guidelines instead of progressing to step 3. In the complainant's view, Alvesco should only be used at step 2 of the BTS guidelines in the small number of patients who were uncontrolled with BDP therapy (the PCT's first choice inhaled steroid) because compliance was compromised by oral side effects.

Altana's response stated that the representative who had spoken to the practice nurse had understood that the complainant had endorsed the use of Alvesco once BDP had not been successful and before resorting to combination therapy. This was not so.

The promotional literature for Alvesco placed the product as an alternative to BDP at step 2 of the BTS guidelines in patients uncontrolled on BDP without any reference to poor compliance. The BTS guidelines, however, did not indicate that patients uncontrolled at step 2 on one inhaled steroid should try an alternative inhaled steroid; patients in whom asthma was uncontrolled should progress to step 3. The Panel noted that Altana had referred to the 'tight confines of the agreement with the complainant'. In the Panel's view, however, the promotional literature positioned Alvesco for a wide range of patients.

The Panel considered it unlikely that the complainant, head of prescribing at a PCT, would endorse a course of action which was not referred to in the BTS guidelines and this was supported by the complainant's comments. The complainant's name had been used, with his permission, by a representative during the course of promoting Alvesco. The promotional literature positioned Alvesco in a way which was not referred to in the BTS guidelines, ie as an alternative for use in any patient uncontrolled on BDP. The Panel thus considered that, on the balance of probability, the practice nurse had

been led to believe that the complainant endorsed Altana's positioning of Alvesco which was not so. The Panel considered that the representatives had failed to maintain a high standard of ethical conduct and had failed to comply with all relevant requirements of the Code. Formal permission had not been obtained in relation to the quotation used by the representative with the practice nurse, ie the misquotation. Breaches of Clauses 7.2, 7.4, 9.1, 11.3 and 15.2 were ruled. The Panel ruled no breach of Clause 7.6 as that clause related to references to published studies.

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.

#### **APPEAL BY ALTANA**

Altana had serious concerns about the decisions of the Panel, having regard to the balance of the evidence available to it. For example, the whole complaint was based on a piece of unattributed hearsay from an unidentified individual.

Secondly, Altana was equally concerned to learn of the serious breaches of the complaints procedure in this case. These were not just technical irregularities: they significantly disadvantaged Altana and it was clear that they materially affected the outcome of the Panel's deliberations.

Altana strongly supported the ABPI and was happy to be subject to the rules and procedures for complaint handling. However, the Authority clearly had a duty to deal with complaints under the procedure in a fair manner. Regrettably, in this instance, Altana believed strongly that the complaints procedure had been dealt with in a manner that was grossly unfair to the company.

Altana submitted that the complaint relied entirely upon the content of a meeting between an Altana representative and an unnamed nurse in the local area on an unspecified date. There was no dissatisfaction with the conduct of two other Altana representatives at a meeting with the complainant.

Altana noted that the complainant had stated that he 'learned' of the meeting between 'a nurse' and an Altana representative and that he was 'incensed' to learn what was allegedly said by the nurse. The alleged content of this meeting formed the basis of his complaint. The complainant did not name his source (other than as a nurse in a GP surgery in a local area) nor crucially did he indicate whether this was reported directly to him by the nurse or whether via one or more other persons. He gave no details about the time or the place of the meeting.

Altana submitted that there were two obvious issues which applied to a complaint of this nature. Firstly without knowing the basic details of the meeting the company could not introduce the contemporaneous meeting notes made by the representative and entered into a database (as per company policy) as a reasonable counterbalance to this unsupported 'hearsay' provided by the complainant. This was unfair and put Altana at an extreme disadvantage. Secondly, the complaint was based on what the

complainant learnt had been said by an unidentified person. This was highly unsatisfactory. No indication was given how he learnt about what had been said, nor who told him. The story might have come through any number of intermediaries. In most tribunals such uncorroborated hearsay evidence was treated with extreme caution and not given the same weight as more direct evidence.

Altana submitted that the representative indicated that in meetings with nurses in the local area during the possible timeframe for the 'undisclosed' meeting he did not deviate from the prescribed Altana position that Alvesco was for 'step 2 asthma as an alternative to BDP, if management using BDP had been unsuccessful'.

Altana submitted that in cases such as this where, through lack of available evidence, one could not reasonably discern the content of a meeting, then the Panel should base its ruling on the hard evidence submitted. These were the Alvesco promotional materials and the SPC used by the representative during promotional calls. These had been reviewed by the Panel. Altana submitted that the promotional materials were consistent with the SPC for Alvesco, the Code and the BTS guidelines.

Altana noted the Panel stated that 'A judgement had to be made on the available evidence bearing in mind that extreme dissatisfaction was usually necessary on the part of an individual before he was moved to actually submit a complaint'. However when the 'extreme dissatisfaction' was based upon unsupported 'hearsay' from an undisclosed third party it was surely inappropriate to allow such tenuous sentiment to form any part of the consideration, especially when it appeared to weigh so heavily in favour of the complainant.

Altana submitted that given the paucity of confirmed evidence of a material breach of the Code at the Panel level (other than the literature submitted by Altana), then the Panel's ruling should be reversed. Not only was the Panel's ruling based on poor evidential foundations, but the position was exacerbated by the manner in which the complaint had been handled.

Altana was also deeply concerned that the Panel had prejudiced the outcome of this case by not conducting its investigation according to documented procedures. The Panel had a duty to provide a fair and balanced process to all parties during its work. There were three serious breaches of the Constitution and Procedure as follows:

1 Following receipt of the complaint, Altana supplied a formal response to the Authority. This response (which included confidential materials) was shown in its entirety to the complainant. There was no provision for this under Paragraph 6.1 of the Constitution and Procedure. This allowed the complainant to refine his complaint and expand upon it using the contemporaneous notes written by Altana employees as the template for this adaptation.

2 Where materials viewed by the respondent were considered to be confidential, there was a procedure for determining whether or not they ought to be provided to the complainant. There was no indication that such a procedure was ever followed in this case.

3 More seriously, however, the complainant's comments upon Altana's response were not shown to Altana prior to the Panel making a ruling. This was a clear breach of Paragraph 6.1 of the Constitution and Procedure and seriously prejudiced the outcome of the case. As had been noted in the introduction above, Altana was denied the opportunity to respond to the expanded allegations. On any basis, this was grossly unfair.

Altana submitted that the unsatisfactory nature of the evidence on which the original complaint was based was therefore compounded by the manner in which the procedures were not followed

In summary, Altana submitted that; there was a lack of substantiated evidence about the contents of the meeting between an Altana representative with an unnamed nurse in the local area. The evidence relied upon by the complainant was unsatisfactory and based on unsourced and uncorroborated hearsay; these evidential failings had been exacerbated by significant breaches of procedure by the Panel when handling the complaint, which had caused substantial unfairness and seriously prejudiced the outcome. Accordingly, Altana submitted that this judgment must be overturned in its entirety.

#### **COMMENTS FROM THE COMPLAINANT**

The complainant noted that Altana appealed on two fronts, firstly on the evidence and secondly that procedures were not followed by the Panel. Accordingly, the complainant restricted his response to countering the evidential areas.

The complainant noted that Altana had re-stated its position for Alvesco, which was for 'step 2 asthma as an alternative to BDP, if management using BDP had been unsuccessful'. Additionally, Altana did not deny that the name of the PCT, and the complainant's in particular, were used during this promotional activity.

The complainant stated that his complaint was based upon the fact that Altana was using his name in combination with a product positioning statement with which he entirely disagreed. Altana's placement was not in keeping with the current BTS guidelines and the complainant would never endorse a product recommendation that was outside such a well recognised national guideline.

The complainant noted that the Panel ruled breaches in Clauses 7.2, 7.4, 9.1, 11.3 and 15.2. Clause 11.3 related to using quotations with formal permission, the complainant had not given Altana permission to use his name or the name of the PCT in the endorsement or promotion of Alvesco but merely to state that they had met.

The complainant noted that Clauses 7.2 and 7.4 related to promotional claims being accurate and capable of substantiation. Altana disputed the content of his meeting with Altana and about his endorsement of Alvesco were inaccurate and could not be formally substantiated. Altana's account of the meeting was at odds with the account previously submitted by the complainant. Nonetheless, the complainant confirmed that it was his extreme dissatisfaction when he learned that he was being

quoted in support of a product placement he would never endorse, that prompted him to complain.

The complainant noted that the final two breaches (Clauses 9.1 and 15.2) related to maintenance of high standards overall and for representatives in particular. Given the information above he contended that the original rulings were appropriate on all counts, formal permission was not obtained; information used was misleading and could not be substantiated and high standards were not maintained. As such the original rulings should be sustained.

Finally, the complainant noted that much of Altana's appeal was based upon the unknown identity of the practice nurse who met with the Altana representative and the mode of communication of the content of this meeting to him. The complainant confirmed that the nurse in question met with the Altana GP representative at the end of June 2006. She telephoned the complainant directly to ask for his confirmation, or otherwise, of the content of this meeting.

The complainant provided a copy of a letter from the nurse in question giving her account of the meeting and the telephone call immediately after, that would corroborate his version of events. The complainant trusted that this letter would confirm that the 'unnamed nurse' existed and moreover that the meeting described in his complaint occurred.

In summary, the complainant appreciated fully the difficulties in reaching a decision when presented with two conflicting accounts of the same meeting. The complainant submitted that if he had met with representatives from Altana and was in agreement with the positioning of its product he would grant permission to promote it in combination with his name and that of the PCT. The very fact that in this instance the complainant had felt compelled to complain and devote several hours to submitting his complaint and responding to this appeal must give some inclination to the level of dissatisfaction he felt in regard to the conduct of the Altana representatives. As a direct consequence of this incident the complainant categorically told all representatives with whom he met that they could not use his name or the name of the PCT in any activities, promotional or otherwise. The representatives were told this at the beginning of the meeting and given the opportunity to leave if it was not acceptable to them. This was now PCT policy.

#### **APPEAL BOARD RULING**

The Appeal Board noted that the complainant had alleged that, following a meeting with two Altana representatives, he had been misquoted by a third. The complainant had stated that during the meeting with the Altana representatives he had repeatedly been asked to endorse Alvesco after BDP as an alternative to other steroids and to step 3 of the BTS guidelines. The complainant had submitted that this request had been repeatedly refused. However, the complainant had found out that another Altana representative had subsequently used his name to

endorse this product positioning when discussing Alvesco with a practice nurse. It appeared that the complainant had not met with the representative who had talked to the practice nurse and so any information that that representative had must have come from those who met with the complainant.

The Appeal Board noted that one of the representatives who had met with the complainant had emailed an account of that meeting to, *inter alia*, the representative who had subsequently visited the practice nurse. It was noted in the email that the meeting with the complainant had lasted an hour and a half during which time he had 'finally come round to agreeing that as long as a GP had tried BDP first of all and wanted to then use Alvesco as their next step particularly instead of using a combination then he was happy with that'. It was also noted in the email that the complainant was not willing to put something about Alvesco in a newsletter. The email later advised the reader 'to really spread the word across [local] GPs and [practice nurses] that our positioning of 'after BDP and before combinations' is one that [the complainant] and the PCT supports and endorses. [The complainant] eventually stated that those patients who are poor compliers or potentially poor compliers, those who have oral side effects, those who are fearful of [inhaled corticosteroids], those who would benefit from the convenience of OD (all the patient types we talked to him about) are all patients that [he] is happy for Alvesco to be used on. If Alvesco is used rather than a combination then he is very happy with that. He confirmed he would not come down on any GP who uses Alvesco after BDP especially if they have a rationale for doing so'. The email concluded by '... we can really blitz [certain areas] and drive the business forward'.

The Appeal Board considered that the email showed that the representative had had to work extremely hard to get any agreement out of the complainant. Agreements gained in such circumstances should be treated with caution. The Appeal Board considered that following such a protracted discussion the representative should have written to the complainant so that both parties could confirm their understanding of what had been agreed. It was beholden upon representatives to be abundantly clear when using the names of health professionals to endorse a promotional message. In circumstances where companies sought to gain the endorsement of public bodies ie PCTs and the like, for their products, the Appeal Board considered that they would be well advised to confirm formal agreement before making such endorsement known.

On the evidence before it, the Appeal Board was satisfied on the balance of probabilities that the complainant's views about the positioning of Alvesco had been misrepresented. The Appeal Board upheld the Panel's rulings of breaches of Clauses 7.2, 7.4, 9.1, 11.3 and 15.2 of the Code. The appeal was thus unsuccessful.

<b>Complaint received</b>	<b>9 June 2006</b>
<b>Case completed</b>	<b>25 September 2006</b>