CASE AUTH/2320/5/10

ANONYMOUS v ASTRAZENECA

Promotion of Symbicort

An anonymous, uncontactable complainant alleged that incorrect information had been given by an AstraZeneca representative during the course of promoting Symbicort Turbohaler (budesonide plus formoterol). Symbicort was indicated in the regular treatment of asthma where the use of a combined inhaled corticosteroid and long-acting beta2-agonist was appropriate.

The complainant noted that the representative stated that a pressurised metered dose inhaler (pMDI), with good technique, delivered only 10-15% of the dose to the lungs compared with 30% achieved with the Turbohaler. The impression given was that the Turbohaler always achieved better lung deposition than an MDI. A leavepiece, entitled 'Clinically Effective Inspiratory Flow', stated: 'Turbohaler is effective at a peak inspiratory flow (PIF) of around 30L/min, delivering 15% of dose to the lung (a pressurised MDI, with good inhalation technique, delivers 10 -15%).' and 'Doubling the PIF to 60L/min increases the lung deposition to about 30%'.

The complainant looked into the matter and noted that lung deposition with MDIs containing ciclesonide was over 50% and with beclometasone was either 36% or 52%, depending on whether the MDI was Clenil or Qvar. Consequently, the complainant was very cautious about the information provided by AstraZeneca and its representative.

The detailed response from AstraZeneca is given below.

The Panel noted AstraZeneca's submission that the bracketed part of the claim 'Turbohaler is effective at a peak inspiratory flow (PIF) of around 30L/min, delivering ~15% of nominal dose to the lung (a pressurised MDI, with good inhalation technique, delivers 10-15%)' was true for the majority of pMDIs used in the UK but not for Alvesco, Clenil and Qvar. The claim, however, was not qualified, it appeared that no pMDI delivered more than 10-15% of the nominal dose which was not so; Alvesco delivered over 50%, Clenil 36% and Qvar 52%.

The Panel did not accept AstraZeneca's submission that, taken in its entirety, health professionals would understand the claim to mean that at a PIF of around 30L/min the amount of medicine delivered to the lung by a Symbicort Turbohaler was comparable to that of the more common pMDIs. It appeared that at a PIF of around 30L/min the dose delivered from the Turbohaler was comparable to that delivered by all pMDIs which was not so. The Panel considered that the claim as a whole presented a misleading comparison which could not be substantiated. Breaches of the Code were ruled.

The Panel noted that the claim 'Doubling the PIF to 60L/min increases lung deposition to about 30%' was true for the Turbohaler. However, given the context in which it appeared ie immediately below the comparative claim discussed above, it appeared that at a PIF of 60L/min lung deposition with a Turbohaler would be better than with all pMDIs which was not so. Breaches of the Code were ruled.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of the Code was ruled which was upheld on appeal by AstraZeneca.

The Panel noted that the complainant alleged that the representative had stated that a pMDI with good technique delivered only 10-15% of the dose to the lungs compared with 30% achieved with the Turbohaler. The Panel considered that it was difficult to know what had been said between the parties; a judgement had to be made on the available evidence. The complainant was anonymous and non-contactable and had not identified the representative. The Panel considered that the statement allegedly made by the representative was misleading. Nonetheless, it was based on the claims in the leavepiece and, in that regard, the representative was only following his/her brief. The Panel considered that the matter was covered by its rulings of breaches of the Code above and thus the Panel ruled no breach of the Code.

An anonymous, uncontactable complainant alleged that information given by a representative of AstraZeneca UK Limited, during the course of promoting Symbicort Turbohaler (budesonide plus formoterol), was incorrect. Symbicort was indicated in the regular treatment of asthma where the use of a combined inhaled corticosteroid and long-acting beta2-agonist was appropriate.

COMPLAINT

The complainant noted that the representative stated that a pressurised metered dose inhaler (pMDI), with good technique, delivered only 10-15% of the dose to the lungs compared with 30% achieved with the Turbohaler. The impression given was that the Turbohaler always achieved better lung deposition than an MDI. The representative provided a leavepiece entitled 'Clinically Effective Inspiratory Flow' (ref CZ001110SYMB) which stated:

'Turbohaler is effective at a peak inspiratory flow (PIF) of around 30L/min, delivering 15% of dose to the lung (a pressurised MDI, with good inhalation technique, delivers 10 -15%).'

and

'Doubling the PIF to 60L/min increases the lung deposition to about 30%.'

The complainant looked into the matter and noted that lung deposition with MDIs containing ciclesonide was over 50% and with beclometasone was either 36% or 52%, depending on whether the MDI was Clenil or Qvar.

Consequently, the complainant was very cautious about the information provided by AstraZeneca and its representative.

When writing to AstraZeneca, the Authority asked it to respond in relation to the requirements of Clauses 7.2, 7.3, 7.4, 9.1 and 15.2 of the Code.

RESPONSE

AstraZeneca stated that the leavepiece was developed to inform health professionals about the range of clinically effective peak inspiratory flow (PIF) rates for the Symbicort Turbohaler device in asthmatic patients.

'Turbohaler is effective at a peak inspiratory flow (PIF) of around 30L/min, delivering ~15% of nominal dose to the lung (a pressurised MDI, with good inhalation technique, delivers 10-15%)'

The first part of this claim stated that the Symbicort Turbohaler was effective at a PIF of around 30L/min and delivered approximately 15% of nominal dose to the lung. Efficacy at flow rates around 30L/min had been demonstrated in clinical studies (Engel *et al* 1992, Pedersen *et al* 1990).

The part of the claim in brackets 'a pressurised MDI, with good inhalation technique, delivers 10-15%' referred to the fact that 10 -15% of the metered dose of the pharmacological agent from the more commonly used types of pMDI was delivered to the lung.

AstraZeneca noted that the pMDI market was segmented into two parts: those pMDIs which delivered approximately 10 -15% of pharmacological agent to the lungs and those which delivered a higher percentage of pharmacological agent to the lungs including Alvesco (ciclesonide) at over 50%, Clenil (beclometasone) at 36%, and Qvar (beclometasone) at 52%, all listed by the complainant. This was important because the pMDIs which delivered a higher percentage of pharmacological agent to the lungs represented only a small proportion of overall pMDI usage. Data from IMS in March 2009 which measured UK sales of these less common, by market share, pMDIs showed that they only made up approximately 10% of the total pMDI market with the more common pMDIs making up approximately 90% of sales. IMS data from April 2010 demonstrated that these less common pMDIs still only accounted for approximately 15% of the market, with the remainder made up of the more common pMDIs.

Indeed, in the scientific literature it was well established that the more common pMDIs delivered in the range of approximately 10-15% of the nominal dose, with similar figures quoted in recent peer-reviewed publications. Lavorini and Fontana (2009) stated that '… no more than ~20% of the emitted dose reaches the lungs'. Vincken *et al* (2010) stated that 'Attaching a spacer to a pMDI also filters out the non-respirable particles and slows down the emitted aerosol, such that pulmonary deposition increases from around 10% using a pMDI to 20% or more using a pMDI plus spacer'.

The fact that in clinical practice the more common pMDIs required separate consideration was reflected in the most recent British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) guidelines. Section 5.4, which referred to relative effects of different inhaled steroid pMDI products, stated, 'It is important to differentiate Qvar from other HFA beclometasone products. Many studies now show Qvar equivalence at half the dose of CFC BDP, whereas non-Qvar HFA BDP pMDI products show equivalence at 1:1 dosing'.

Therefore, it was clear that a health professional reviewing this item would assume that the claim at issue compared Symbicort Turbohaler with these more common pMDIs which made up the vast majority of the pMDIs and not with the less common pMDIs such as Qvar and Clenil as alleged by the complainant.

Therefore, this claim in its entirety would be understood by the health professional to indicate that at a PIF of around 30L/min the amount of drug delivered to the lung by the Symbicort Turbohaler was comparable to that of the more common pMDIs as outlined above.

Relevant to this, Borgstrom *et al* (1994), which was cited in the leavepiece, stated that 'Drug deposition in the lungs at 36L/min is at least as good with Turbohaler as with a correctly used pressurised MDI …'. This was further substantiated in a clinical review which was also referenced in the leavepiece and which examined delivery devices for inhaled asthma drugs. The authors stated 'At lower flow rates the deposition from Turbohaler resembles that seen when a patient with good coordination uses a classic pMDI' (Selroos *et al* 1996).

Therefore, although the complainant questioned the accuracy of the claim, and referred to examples of the less common pMDIs which delivered higher percentages of medicine deposition in the lungs, over 50% for Alvesco (ciclesonide), 36% for Clenil

(beclometasone) and 52% for Qvar (beclometasone), without further qualification the health professional would interpret the claim to refer to the more common pMDIs.

Based on the above information, AstraZeneca submitted that the claim was a fair and balanced reflection of the overall evidence relating to lung deposition with the Symbicort Turbohaler and the more common pMDIs and was capable of substantiation. Therefore, AstraZeneca did not consider that Clauses 7.2, 7.3 or 7.4 had been breached.

Furthermore, AstraZeneca did not believe that the use of the claim in the leavepiece did not maintain high standards and was in breach of Clause 9.1.

'Doubling the PIF to 60L/min increases the lung deposition to about 30%'

This claim referred to the fact that increasing the PIF to 60L/min increased the lung deposition of Symbicort Turbohaler to about 30%. Thorsson *et al* (1994) determined the pulmonary and systemic availability of budesonide after inhalation from the Symbicort Turbohaler, and also from a pMDI in healthy volunteers. The subjects were trained to breathe out to residual volume, and then to inhale at a flow of 60L/min for Turbohaler, and 30L/min for pMDI. The bioavailability was calculated using two methods. The pulmonary availability, calculated using the first method, was 32% and 15% for Symbicort Turbohaler and pMDI, respectively, and using the second method, 32% and 18%, respectively.

Furthermore, Selroos *et al* stated that most pMDIs gave deposition figures of around 10 -15% of the metered dose (at a flow rate of around 30L/min), whilst the use of the Turbohaler resulted in deposition of 20 - 35% of the metered dose at a flow of ≥40L/min.

Therefore, with reference to the Symbicort Turbohaler this claim was fair, balanced, not misleading and capable of substantiation. AstraZeneca did not believe that there had been a breach of Clauses 7.2, 7.3, or 7.4. Furthermore, AstraZeneca did not believe that the use of the claim in the leavepiece did not maintain high standards, relating to Clause 9.1.

AstraZeneca noted that the representative had allegedly stated that a pMDI, with good technique, delivered only 10 -15% of the dose to the lungs, compared with the 30% achieved with the Turbohaler.

AstraZeneca further noted that the complainant had not identified the representative. Without further information, it was not possible to investigate this aspect of the complaint, including any specific training the representative might have received. However, AstraZeneca provided a copy of a relevant training presentation ('Devices' Powerpoint presentation, ref CZ003316, date of preparation, February 2010) that was used as part of the induction programme for all representatives in relation to the use of inhalers, although the company did not have briefing materials for the specific leavepiece. This training on relevant aspects of inhaler devices gave the representatives the necessary knowledge to be able to deliver the content of materials, such as the leavepiece, in a compliant and factual fashion. For example, slides 12-31 of the presentation provided information about inhaler delivery systems including pMDIs and dry powder devices (DPIs). Of particular relevance to the current complaint, slide 29 informed the representative about inspiratory flow rate and lung deposition with the Symbicort Turbohaler: '30L/min is the inspiratory flow rate needed to achieve a clinical response with the TBH = 15% deposition, as IFR increases, the amount of drug deposited increases, up to a maximum of around 30%, at the IFR of 60L/min'. Also of specific relevance to the contested claims, slide 30 referred to lung deposition levels with different devices including Seretide Evohaler (pMDI), Seretide Accuhaler (DPI) and Symbicort Turbohaler (DPI).

AstraZeneca considered that on the balance of probabilities, taking into account the content of the leavepiece and relevant associated training materials, it was likely that the representative would have stated the claim as set out in the leavepiece that was the subject of this complaint: 'Turbohaler is effective at a peak inspiratory flow (PIF) of around 30L/min, delivering ~15% of nominal dose to the lung (a pressurised MDI, with good inhalation technique, delivers 10-15%)'.

Therefore, taking all the above evidence into account, and on the balance of probabilities in terms of what the representative was likely to have said to the complainant, and the content of the leavepiece, AstraZeneca did not understand how the complainant was left with the impression that the Turbohaler always achieved better lung deposition than an MDI. This was never AstraZeneca's intention and such a claim had never formed any part of the promotional activity for Symbicort Turbohaler in the UK.

AstraZeneca did not believe that the representative had not maintained high standards and therefore did not believe that there had been a breach of Clause 15.2. The company also strongly considered that there had been no breach of Clause 9.1 relating to high standards.

In summary, AstraZeneca did not believe that there had been breaches of Clauses 7.2, 7.3, 7.4, 15.2 and 9.1.

PANEL RULING

The Panel noted AstraZeneca's submission that the bracketed part of the claim 'Turbohaler is effective at a peak inspiratory flow (PIF) of around 30L/min, delivering ~15% of nominal dose to the lung (a pressurised MDI, with good inhalation technique,

delivers 10-15%)' was true for the majority of pMDIs used in the UK but not for Alvesco, Clenil and Qvar. The claim, however, was not qualified, it appeared that no pMDI delivered more than 10-15% of the nominal dose which was not so; Alvesco delivered over 50%, Clenil 36% and Qvar 52%.

The Panel did not accept AstraZeneca's submission that, taken in its entirety, health professionals would understand the claim to mean that at a PIF of around 30L/min the amount of medicine delivered to the lung by a Symbicort Turbohaler was comparable to that of the more common pMDIs. It appeared that at a PIF of around 30L/min the dose delivered from the Turbohaler was comparable to that delivered by all pMDIs which was not so. The Panel considered that the claim as a whole presented a misleading comparison which could not be substantiated. Breaches of Clauses 7.2, 7.3 and 7.4 were ruled.

The Panel noted that the claim 'Doubling the PIF to 60L/min increases lung deposition to about 30%' was true for the Turbohaler. However, given the context in which it appeared ie immediately below the comparative claim discussed above, it appeared that at a PIF of 60L/min lung deposition with a Turbohaler would be better than with all pMDIs which was not so. Breaches of Clauses 7.2, 7.3 and 7.4 were ruled.

The Panel noted its rulings above and considered that high standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that the complainant alleged that the representative had stated that a pMDI with good technique delivered only 10-15% of the dose to the lungs compared with 30% achieved with the Turbohaler. The Panel considered that it was difficult to know what had been said between the parties; a judgement had to be made on the available evidence. The complainant was anonymous and non contactable and had not identified the representative. The Panel considered that the statement allegedly made by the representative was misleading. Nonetheless, it was based on the claims in the leavepiece and, in that regard, the representative was only following his/her brief. The Panel considered that the matter was covered by its rulings of breaches of the Code above and thus the Panel ruled no breach of Clause 15.2.

APPEAL BY ASTRAZENECA

AstraZeneca noted that although it had accepted the rulings of breaches of Clauses 7.2, 7.3, and 7.4 it did not believe that the reasons set out by the Panel for those rulings were grounds for concluding that high standards were not maintained.

AstraZeneca submitted that, as stated previously, as the complainant had not named the representative in question and as the complainant was anonymous and non-contactable it was not possible to investigate this aspect of the complaint further.

Therefore, AstraZeneca agreed with the Panel's ruling that the matter of what was allegedly stated by the representative was covered by its rulings of the breaches of the Code in relation to the claims in the leavepiece. AstraZeneca therefore restricted its comments below to considerations around the claims in the leavepiece and not to any alleged representative activities.

AstraZeneca noted that Clause 9.1 stated that 'high standards must be maintained at all times' which it believed to be applicable in relation to the content of the challenged leavepiece. The supplementary information to Clauses 9.1 and 9.2 of the Code stated:

'The special nature of medicines and the professional audience to which the material is directed require that the standards set for the promotion of medicines are higher than those which might be acceptable for general commodity advertising.

It follows therefore that certain types, styles and methods of promotion, even where they might be acceptable for the promotion of products other than medicines, are unacceptable.

These include:

- the display of naked or partially naked people for the purpose of attracting attention to the material or the use of sexual imagery for that purpose
- 'teaser' advertising whereby promotional material is intended to 'tease' the recipient by eliciting an interest in something which will be following or will be available at a later date without providing any actual information about it
- the provision of rubber stamps to doctors for use as aids to prescription writing
- the provision of private prescription forms preprinted with the name of a medicine.'

AstraZeneca submitted that although the supplementary information applied specifically to suitability and taste it provided examples of the types of situations where a breach of Clause 9.1 would be applicable. In view of this, although AstraZeneca accepted the Panel's rulings of breaches of Clauses 7.2, 7.3, and 7.4 in relation to the use of the claims in the leavepiece it did not understand in what way the considered use of the claims in the leavepiece compromised the required high standards set out in the Code. AstraZeneca submitted that it had carefully considered the evidence that underpinned the claims at issue and thus a breach of Clause 9.1 was not applicable in this particular case.

AstraZeneca submitted that the leavepiece at issue was developed to inform health professionals of the range of clinically effective PIF rates for the Symbicort Turbohaler device in asthmatic patients.

The complaint referred to two adjacent claims in the leavepiece.

AstraZeneca noted that the first claim at issue was 'Turbohaler is effective at a peak inspiratory flow (PIF) of around 30L/min, delivering ~15% of nominal dose to the lung (a pressurised MDI, with good inhalation technique, delivers 10-15%)' The first part of this claim stated that the Symbicort Turbohaler was effective at PIF of around 30L/min and delivered approximately 15% of nominal dose to the lung. Efficacy at flow rates around 30L/min has been demonstrated in clinical studies (Engel *et al*, Pedersen *et al*). The bracketed part of the claim 'a pressurised MDI, with good inhalation technique, delivers 10-15%' referred to the fact that 10-15% of the metered dose of the pharmacological agent from the more commonly used type, or conventional, pressurised metered dose inhaler (pMDI) was delivered to the lung.

AstraZeneca noted that the pMDI market could be segmented into two parts: the more common pMDIs which delivered approximately 10-15% of pharmacological agent to the lungs, made up the large proportion of the marketplace (also known as conventional pMDIs which were the 'fine' particle inhalers (range ~3-5 microns)), and those which delivered a higher percentage of pharmacological agent to the lungs including Alvesco at over 50%, Clenil at 36%, and Qvar at 52%, all listed by the complainant, which made up a small proportion of the marketplace. Alvesco, Clenil and Qvar were all extra-fine particle inhalers (range ~1-3 microns) which helped to explain their higher levels of lung deposition compared with the conventional pMDIs.

AstraZeneca submitted that the extra-fine particle pMDIs which delivered a higher percentage of pharmacological agent to the lungs represented only a small proportion of overall pMDI usage. IMS data in March 2009 showed that they only made up approximately 10% of the total pMDI market, with the conventional pMDIs making up approximately 90% of sales. IMS data from April 2010 demonstrated that these less common extra-fine particle pMDIs still accounted for approximately only 15% of the pMDI market, with the more common conventional pMDIs accounting for approximately 85% of the pMDI market (April 2010 data provided).

AstraZeneca submitted that in the scientific literature it was well established that the conventional pMDIs delivered approximately 10-15% of the metered dose. Thorsson *et al* reported, in a study comparing the Turbohaler with a pMDI, that 'the pulmonary availability, calculated relative to metered-doses and assuming an oral availability of 13%, was 32% (geometric mean, range 16-59%) for Turbohaler and 15% (range 3-47%) for pMDI'. Additionally, Barry and O'Callaghan (1996) examined the use of spacer devices with MDIs, and stated that 'Proper use requires coordination of inhalation and MDI actuation but, even with optimum technique, less than 15% of the actuated dose reaches the lungs.' This was further substantiated in a clinical review (Selroos *et al*) referenced in the leavepiece, which examined delivery devices for inhaled asthma medicines. Here, it stated: 'At lower flow rates the deposition from Turbohaler resembles that seen when a patient with good coordination uses a classic pMDI'. Further to this, Lavorini and Fontana stated that '…no more than ~20% of the emitted dose reaches the lungs.' Vincken *et al* stated that 'Attaching a spacer to a pMDI also filters out the non-respirable particles and slows down the emitted aerosol, such that pulmonary deposition increases from around 10% using a pMDI to 20% or more using a pMDI plus spacer.'

AstraZeneca further noted that Newman and Chan (2008) reviewed data around fine particle fractions and lung deposition across 33 different inhalers including pMDIs and showed that the vast majority of pMDIs (CFC and HFA) tested were clustered around the 10-15% lung deposition range. The only pMDI in this analysis with a significantly higher lung deposition value contained an add-on device and therefore was not relevant to this discussion.

AstraZeneca submitted that the fact that in clinical practice these less common, extra fine particle pMDIs required separate consideration was reflected in the most recent BTS/SIGN guidelines (2009) Section 5.4, which referred to relative effects of different inhaled steroid pMDI products, stated, 'It is important to differentiate Qvar from other HFA beclometasone products. Many studies now show Qvar equivalence at half the dose of CFC BDP, whereas non-Qvar HFA BDP pMDI products show equivalence at 1:1 dosing'.

Therefore, AstraZeneca submitted that as stated above, the conventional pMDIs were so widely used and prescribed that it considered that health professionals would assume that the contested claim compared Symbicort Turbohaler with these pMDIs (which generally had a lung deposition of around 10-15%), and not with all pMDIs which would include the extra-fine particle pMDIs such as Qvar, Alvesco and Clenil as mentioned by the complainant.

Finally, AstraZeneca also noted the use of the indefinite article 'a' in the bracketed section of the claim. In its ruling the Panel assumed that this claim referred to all pMDIs which was not so. AstraZeneca did not intend to imply that all pMDIs had a lung deposition level of 10-15%. In contrast, the use of the indefinite article ensured exactly the opposite effect, to make clear that this was not intended to be a general statement applicable to all pMDIs. The use of the indefinite article was consistent with AstraZeneca's intention to refer to the more common conventional pMDIs as stated above.

On this basis AstraZeneca intended this claim, in its entirety, to be understood by the health professional to indicate that at a PIF of around 30L/min the amount of medicine delivered to the

lung by the Symbicort Turbohaler was comparable to that of the far more common conventional pMDIs as outlined above. In support of this, Borgstrom *et al* which was referenced in the leavepiece, stated that 'Drug deposition in the lungs at 36 L/min is at least as good with Turbohaler as with a correctly used pressurised MDI ...'.

AstraZeneca accepted the Panel's rulings of breaches of Clauses 7.2, 7.3 and 7.4 but did not agree that this claim was a breach of Clause 9.1 relating to high standards based on the above considerations.

AstraZeneca noted the second claim stated 'Doubling the PIF to 60L/min increases the lung deposition to about 30%'. The Panel had stated that given the context in which this claim appeared ie immediately below the comparative claim discussed above, 'it appeared that at a PIF of 60L/min lung deposition with a Turbohaler would be better than with all pMDIs which was not so'. However, this claim was presented as a separate bullet and was a standalone claim. The intention was that this claim referred to the fact that increasing the PIF to 60L/min increased the lung deposition of Symbicort Turbohaler to about 30%. It was not intended to imply that Symbicort Turbohaler at 60L/min would be better than all pMDIs.

Therefore, although AstraZeneca accepted the Panel's view that the claim could be interpreted in a different way and it had therefore ruled breaches of Clauses 7.2, 7.3 and 7.4 of the Code, AstraZeneca did not believe that it followed that this was an indication that the use of this claim, or indeed the use of both claims in the same leavepiece, constituted a breach of Clause 9.1 relating to high standards based on the above.

To conclude, given the intent of the provision of Clause 9.1, AstraZeneca submitted that a breach of Clause 9.1 was not applicable in this case. AstraZeneca accepted that irrespective of the above considerations relating to the use of the claims at issue in the leavepiece, the Panel had ruled breaches of Clauses 7.2, 7.3, and 7.4. However, AstraZeneca did not believe that breaches of Clause 7 automatically constituted a breach of Clause 9.1.

APPEAL BOARD RULING

The Appeal Board noted from the AstraZeneca representatives at the appeal that the Turbohaler had been on the UK market for over 20 years. In that regard the Appeal Board considered that health professionals should be reasonably familiar with the delivery characteristics of the device. Nonetheless, the leavepiece at issue had been developed to be used reactively with any health professionals concerned that the Symbicort Turbohaler might not be clinically effective at low respiratory flow rates. The leavepiece had been approved for use with doctors, pharmacists and nurses.

The Appeal Board noted that AstraZeneca had not made it clear in the leavepiece that the reference to 'a pressurised MDI' only included the more common 'fine' particle inhalers and not also the less common 'extra-fine' particle inhalers. The Appeal Board rejected AstraZeneca's submission that use of the indefinite article 'a' helped in this regard. In the Appeal Board's view 'a pressurised MDI' implied any pressurised MDI chosen at random.

The Appeal Board noted that the leavepiece sought to inform health professionals about the delivery characteristics of the Turbohaler (which had been available in the UK for a number of years) whilst assuming that they were so familiar with the 'extra-fine' particle inhalers (introduced to the UK market after the Turbohaler) that the claims at issue did not need to be qualified. In the Appeal Board's view, although the majority of health professionals would be experienced in the treatment of asthma and would, at least in general, know about the BTS guidelines with regard to Qvar etc, experience and knowledge in that regard could not be assumed and did not mean that unqualified claims were acceptable; it was beholden upon AstraZeneca to ensure that its claims were clear and could not mislead. In that regard the Appeal Board noted that AstraZeneca had accepted the Panel's rulings of breaches of Clauses 7.2, 7.3 and 7.4. The Appeal Board further noted that if prescribers had been misled by the leavepiece, patient safety might have been adversely affected.

The Appeal Board considered that high standards had not been maintained and it upheld the Panel's ruling of a breach of Clause 9.1. The appeal was thus unsuccessful.

Complaint received **21 May 2010**

Case completed **6 August 2010**