COMMUNITY RESPIRATORY NURSE SPECIALIST v GLAXOSMITHKLINE

Promotion of Seretide Accuhaler

A community respiratory nurse specialist complained on behalf of an NHS trust about the conduct of a representative from GlaxoSmithKline and her promotion of Seretide Accuhaler 500mcg (salmeterol/fluticasone). The nurse also complained about a GlaxoSmithKline chronic obstructive pulmonary disease (COPD) audit programme.

Seretide was indicated, *inter alia*, for the symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who had significant symptoms despite regular bronchodilator therapy.

The complainant noted that in October 2006 a GlaxoSmithKline representative told her that Seretide Accuhaler 500mcg was 'licensed' by the Scottish Medicines Consortium (SMC) to be used following treatment with short-acting bronchodilators in the management of COPD and that Symbicort Turbohaler [AstraZeneca's product] was not. The complainant accepted that the SMC advice for both medicines was worded differently but it was not a licence and did not specifically state that Seretide Accuhaler 500mcg could be used after short-acting bronchodilators.

The complainant stated that the information provided by the representative contrasted with the National Institute for Health and Clinical Excellence (NICE) Guideline on COPD (2004) which recommended the addition of an inhaled steroid in patients who were symptomatic despite treatment with short- and long-acting bronchodilators and/or who had FEV1 <50% and had had 2 exacerbations in 12 months requiring antibiotic or oral corticosteroids. At this point the representative failed to mention that this was in keeping with the information given in the GlaxoSmithKline summary of product characteristics (SPC) for Seretide, insisting instead that it was 'licensed' by the SMC to be used as previously stated.

The complainant noted that as the representative was so insistent she had double checked the SMC advice and website and found no evidence for the claim. When the complainant called the representative to ask for evidence for her SMC licence claims she became flustered and apologised if she had misled in anyway and that in fact she meant to say that 'whoever' granted the licence in the first instance stated that it could be used following treatment with short-acting bronchodilators. The complainant asked the representative to provide that evidence. A week later she provided a copy of the SPC.

The complainant stated that reports from several GPs and practice nurses led her to believe that the same information was being commonly given by GlaxoSmithKline representatives.

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 the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint.

The Panel noted that the complainant referred to a discussion about SMC recommendations whereas the representative referred to a discussion about the UK licence. Given the complainant's position the Panel queried whether the representative had been sufficiently clear about the differences between Seretide and Symbicort and the differences between the SPC licensed indications and the SMC guidance.

The Panel noted that training material on the SPC for Seretide in COPD stated that Seretide 500 was aimed at patients who had had their second exacerbation. The training material stressed the two components to the licence ie FEV1 <50% predicted and that the patients still had symptoms even though they had had regular bronchodialator treatment, either long- or short-acting bronchodilators. The training material also stated that the Symbicort licence was more restrictive than Seretide's COPD licence as patients had to be tried on a long-acting bronchodilator before being put on Symbicort. The Panel queried whether when discussing the differences between the indications for Seretide and Symbicort the representatives were sufficiently clear about the similarities ie FEV1 <50% predicted and a history of repeated exacerbations.

Medicines had to be promoted in accordance with their SPCs. SMC and NICE guidance was occasionally different to the SPC indications.

Clearly it was of concern that the complainant had been taken aback by what she referred to as the representative's aggressive sales pitch and that colleagues had allegedly not been given all the details of the indications for Seretide in COPD. However it was not possible to determine where the truth lay. On the basis of the parties' submissions the Panel did not consider that there was sufficient evidence to show that on the balance of probabilities the representative had promoted Seretide outside its SPC or had failed to maintain a high standard of ethical conduct. The Panel ruled no breach of the Code.

The complainant also drew attention to an audit being conducted by GlaxoSmithKline; the audit report did not reflect the advice given in the NICE Guideline, (2004). The complainant was concerned that patients identified as priority patients (by a practice nurse or GlaxoSmithKline nurse advisor) might be unnecessarily prescribed or switched to Seretide.

The Panel noted that in Cases AUTH/1806/3/06 and AUTH/1809/3/06 it had considered a number of nurse audit schemes offered by GlaxoSmithKline including one in COPD. Overall the Panel considered that the services were not unacceptable and were not linked to the prescription of any specific medicine. The decision of what to prescribe lay with the patient's doctor. The services were not an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of the Code had been ruled.

Turning to the case now at issue, Case AUTH/1939/1/07, the Panel noted that the complaint related to the failure of material to reflect the NICE Guideline and that priority patients might be unnecessarily prescribed or switched to Seretide.

The Panel noted that the Code did not require arrangements for services to necessarily follow NICE guidelines. In general the Panel considered that services etc should not advocate use of medicines in a way that would be inconsistent with their SPCs.

The Panel noted GlaxoSmithKline's submission that the search criteria were agreed with the practice. The criteria were MRC dyspnoea score, FEV1, exacerbations within the last 12 months, smoking status, treatment inhaler technique, admissions, oxygen therapy and vaccination. The purpose of the audit was to identify patients that the practice might want to review. This could be done by the practice itself or using a GlaxoSmithKline service. The GlaxoSmithKline service if used would take place in line with an agreed practice protocol. The search identified patients already on combination treatments without identifying the product.

The audit report provided listed 20 priority patients, 16 of whom were currently taking a combination therapy; the report did not identify the patients other than by an identification number nor were details given about which combination therapy they were on. Of the fifteen patients with a recorded FEV1 result, 14 had an FEV1 <50% of predicted. The number of exacerbations in the last 12 months was noted for each patient and in this regard the audit report took account of the NICE Guideline which, unlike the Seretide SPC, put a time limit on exacerbations. None of the 20 patients had had an exacerbation of their disease in the last 12 months. The Panel queried whether it would be appropriate to prescribe Seretide given the lack of exacerbations within the last 12 months when Seretide's indication, *inter alia*, required patients to have repeated exacerbations.

The Panel considered that on the material before it there was insufficient evidence to show that on the balance of probabilities the audit service was an inducement to prescribe, supply, administer, recommend or buy Seretide. No breach of the Code was ruled.

A community respiratory nurse specialist complained on behalf of an NHS trust about the conduct of a representative from GlaxoSmithKline UK Ltd and her promotion of Seretide Accuhaler 500mcg (salmeterol/fluticasone). The nurse also complained about a chronic obstructive pulmonary disease (COPD) audit programme offered by GlaxoSmithKline.

Seretide was indicated, *inter alia*, for the symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who had significant symptoms despite regular bronchodilator therapy.

COMPLAINT

The complainant noted that in October 2006 she was visited by a GlaxoSmithKline representative who stated that Seretide Accuhaler 500mcg was 'licensed' by the Scottish Medicines Consortium (SMC) to be used following treatment with short-acting bronchodilators in the management of COPD and that Symbicort Turbohaler [AstraZeneca's product] was not. The complainant accepted that the SMC advice for both medicines was worded differently but it was not a licence and did not specifically state that Seretide Accuhaler 500mcg could be used after short-acting bronchodilators. A breach of Clauses 3.2 and 7.4 was alleged.

The complainant stated that the information provided by the representative contrasted with the National Institute for Health and Clinical Excellence (NICE) Guideline on COPD (2004) which recommended the addition of an inhaled steroid in patients who were symptomatic despite treatment with short- and long-acting bronchodilators and/or who had FEV1 <50% and had had 2 exacerbations in 12 months requiring antibiotic or oral corticosteroids. At this point she failed to mention that this was in keeping with the information given in the GlaxoSmithKline summary of product characteristics (SPC) for Seretide, insisting instead that it was 'licensed' by the SMC to be used as previously stated. A breach of Clauses 3.2, 7.2 and 8.2 was alleged.

The complainant noted that as the representative was so insistent she had double checked the SMC advice and website the next day and found no evidence for the claim. The complainant called the representative and asked her to provide evidence for her SMC licence claims. She became rather flustered and apologised if she had misled in anyway and that in fact she meant to say that 'whoever' granted the licence in the first instance stated that it could be used following treatment with short-acting bronchodilators. The complainant asked the representative to provide that evidence. A week later she provided a copy of the SPC, dated 29 September 2006. The complainant alleged a breach of Clause 7.4.

The complainant stated that several GPs and practice nurses (who wished to remain anonymous) had reported that they had also been given this information by a GlaxoSmithKline representative (whom they would not identify) which sadly led the complainant to believe that this approach appeared to be commonly employed by local GlaxoSmithKline representatives. The complainant alleged a breach of Clause 2.

When writing to GlaxoSmithKline the Authority asked it to respond in relation to Clauses 9.1, 15.2 and 15.9 of the Code in addition to the clauses cited by the complainant.

RESPONSE

GlaxoSmithKline submitted that the representative had visited the complainant on a number of occasions, when the use of Seretide in both asthma and COPD had been discussed, and all these discussions had been amicable and professional. GlaxoSmithKline had also set up sponsored meetings for the complainant to network with other local practice nurses. On the occasion in question the representative distinctly remembered discussing differences in the UK licence between Seretide and Symbicort in COPD and, in particular, explaining that the Seretide licence allowed use after short-acting bronchodilators, whereas the Symbicort licence only allowed use after long-acting bronchodilators, as well as discussing the clinical evidence to support the Seretide licence. The representative did not recall any mention of the SMC as her objective for the call and the content of the discussion was entirely around the differences between the UK licences for Seretide and Symbicort.

GlaxoSmithKline submitted that during the week following the call, the representative received an email from the complainant (copy provided) which referred to a discussion about the 'SMC recommendation' (as opposed to licence) and the fact that the complainant had checked the SMC website, and actually stated that she 'couldn't find anything'. She went on to ask the representative to either forward a website address or a copy of the SMC document. The complainant did not refer to the NICE guideline in COPD. On receipt of the email the representative telephoned the complainant to explain that she had not referred to the SMC recommendations for Seretide but actually to the UK licence, apologised if she had confused the nurse, and offered to forward further information on the SPCs for both products to clear up the confusion. At this point the representative considered that the nurse was satisfied with her explanation and proposed course of action, and sent a return email (copy provided) to confirm these actions.

GlaxoSmithKline submitted that as promised the representative contacted medical information at GlaxoSmithKline and asked for further information on the respective licences for Seretide and Symbicort in COPD to be sent for her to pass on to the nurse. The representative called the nurse to arrange to drop off the relevant information, the respective SPCs and a Seretide in COPD Clinical Summaries pack, which she did when she visited the nurse at the end of October. At this point the nurse seemed satisfied and had no further questions.

UK licences for Seretide and Symbicort

The SPC for Seretide in COPD stated that 'Seretide is indicated for the symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular bronchodilator therapy', whereas the SPC for Symbicort in COPD stated that Symbicort was indicated for the 'symptomatic treatment of patients with severe COPD (FEV1 <50% predicted normal) and a history of repeated exacerbations, who have significant symptoms despite regular therapy with long-acting bronchodilators'.

GlaxoSmithKline submitted therefore that Seretide could be used in COPD after treatment with regular bronchodilators, ie either short- or long-acting bronchodilators. It was therefore appropriate to discuss the use of Seretide after regular use of short-acting bronchodilators. This was consistent with the representative call. In contrast, the licence for Symbicort in COPD stated explicitly that the product should be used after regular treatment with long-acting bronchodilators. This was an important difference between the products and it was appropriate for representatives to discuss this and make prescribers aware of the different patient populations appropriate for use of these products. Highlighting the fact that Seretide could be used in COPD after only short-acting bronchodilators, compared to Symbicort which could only be used in COPD after long-acting bronchodilators, as was done by the representative, was consistent with the SPCs for both medicines and appropriate.

SMC recommendations for Seretide and Symbicort

GlaxoSmithKline submitted that the SMC recommendation for Seretide in COPD stated merely that 'fluticasone/salmeterol (Seretide) is accepted for use within NHS Scotland for the treatment of patients with severe chronic obstructive pulmonary disease', and the SMC recommendation for Symbicort in COPD stated that 'budesonide/eformoterol (Symbicort) inhaler is accepted for use within NHS Scotland for treating patients with severe chronic obstructive pulmonary disease (COPD) who have significant symptoms despite regular therapy with long-acting bronchodilators'. Once again these recommendations highlighted the important difference between the patient populations appropriate for these products, and reflected their respective licences.

GlaxoSmithKline submitted that it and its representatives knew that SMC recommendations did not constitute a licence, but were in fact a national formulary which determined the use of products in Scotland. As the SMC recommendations made no restrictions on the prescribing of these medicines in Scotland, it was the UK licensed population within which it was appropriate to use these products.

Consequently, although not specifically stated, the SMC recommendation for Seretide would follow the UK licensed population and therefore Seretide was appropriate for patients after treatment with regular bronchodilators. It was therefore accurate to state that the SMC recommendation for Seretide in Scotland was that it was appropriate for treatment after short-acting bronchodilators.

With regard to the complainant's statement that the GlaxoSmithKline representative insisted that Seretide was licensed by the SMC to be used as previously stated, ie that it could be used following treatment with a short-acting bronchodilator, although the GlaxoSmithKline representative did not recall any discussions regarding SMC recommendations for Seretide, the SMC recommendations stated that Seretide should be used in the licensed population, and therefore after short-acting bronchodilators. Therefore although any such statement about a 'licence' would be technically inaccurate with regard to the legal status of the SMC as opposed to the competent authority in terms of responsibility for the grant of a licence, the clinical interpretation of such a statement would not be out of keeping with either the SMC recommendation or the Seretide SPC.

NICE Guideline for COPD

GlaxoSmithKline submitted that the NICE Guideline for COPD (2004) recommended an evidence-based approach to the management of stable COPD. In patients with breathlessness and exercise limitation, NICE initially recommended the use of a short-acting bronchodilator (either a β_2-agonist or an anti-cholinergic) as needed. In patients requiring further treatment, NICE recommended moving to a combined therapy with a short-acting β_2-agonist and a short-acting anti-cholinergic and then, if still symptomatic the use of a long-acting bronchodilator (either a β_2-agonist or an anti-cholinergic). NICE also made specific recommendations for patients with moderate or severe COPD who were still symptomatic despite the above therapies, and advocated the combination of an inhaled corticosteroid and a long-acting bronchodilator. However, NICE also made specific recommendations for frequent exacerbators and stated that inhaled corticosteroids should be prescribed for patients with an FEV1 ≤50% predicted, who had 2 or more exacerbations requiring treatment with antibiotics or oral corticosteroids in a 12 month period, and in its algorithm (provided) stated that these inhaled steroids should be added to optimised bronchodilator therapy with one or more long-acting bronchodilators.

Some difficulties arose because the NICE Guideline was not entirely consistent with the SPC for Seretide. (Additionally NICE guidance was not applicable in Scotland where this complaint had arisen.) Strict adherence to the NICE Guideline required that all patients with moderate or severe COPD (FEV1 ≤50%) only received Seretide when they had had 2 or more exacerbations requiring treatment with antibiotics or oral corticosteroids in a 12 month period and after having received both short- and long-acting bronchodilators. This recommendation was inconsistent with the Seretide SPC which was indicated in patients with FEV1 ≤50% who had a *history of repeated exacerbations* and were symptomatic de*spite regular treatment with bronchodilators*. Therefore, as there was no specified timeframe in the Seretide licence for patients to have had exacerbations, the NICE recommendation that Seretide should be used in patients who had 2 or more exacerbations over a period longer than 12 months was more restrictive than the SPC licence wording. As there was no specified type of bronchodilator which patients should have already received in the licence wording, the NICE recommendations were again more restrictive in this regard as Seretide was indicated in patients who had already received either a short- or a long-acting bronchodilator.

GlaxoSmithKline submitted that unfortunately there seemed to be some confusion on the part of the complainant in this regard as she stated that the NICE recommendation was in keeping with the information given in the Seretide SPC. This was not so since the Seretide SPC and the NICE Guideline clearly indicated that the product should be used in different patient populations. Nevertheless, the SPC took precedence over the NICE Guideline as promotion of a medicine must be in accordance with the terms of its marketing authorization and must not be inconsistent with the particulars listed in its SPC. However, since the patient population recommended in the NICE Guideline was more restricted than that indicated in the Seretide SPC, it was appropriate that whilst responsibly discussing the licensed population for Seretide, representatives also made prescribers aware of the NICE Guideline. Consequently, all primary care representatives had a leavepiece detailing the NICE recommendations and the position of combination treatments in the treatment pathway for use in discussions with health professionals, and in addition the non-promotional respiratory care team had the NICE Guideline included in their detail aid.

GlaxoSmithKline maintained that the representative did not discuss any licensing by the SMC, but rather the actual UK licences. The representative did not recall any discussion regarding SMC, and the email from the complainant referred to SMC recommendations. Furthermore, all discussion entered into by the representative was entirely within the UK licences and SPCs for both Seretide and Symbicort in COPD. The SMC had approved both Seretide and Symbicort for use in Scotland but had not commented further on the indicated population which remained as per the UK licence, therefore discussions of the UK licence were entirely appropriate in this regard. The NICE Guideline was not identical to the licence for Seretide, however it did not take precedence over the SPC and promotion of the licensed indication for Seretide was therefore appropriate, although it was right that representatives made prescribers aware of the NICE recommendations for combination treatments in COPD and appropriate training for representatives and suitable materials had been provided accordingly. Unfortunately, the complainant seemed to be slightly unsure as to the exact nature of the SMC recommendation as regards Seretide, and also the

consistency between the NICE Guideline recommendations and the SPC for Seretide. Furthermore, the complainant's recollection of events seemed to be somewhat different to both that of the representative, and her email to the representative following the call.

Consequently GlaxoSmithKline maintained that all promotion of Seretide by this representative was entirely within the licensed population and the indications of the SPC, therefore there was no breach of Clause 3.2. Furthermore, all the information provided by the representative in this call was in keeping with the Seretide SPC and it followed that all the information, claims and comparisons were accurate and based on an up-to-date evaluation of all the evidence, therefore there was no breach of Clause 7.2. Also, since all the information provided in this call was in keeping with the Seretide SPC all this information was capable of substantiation, therefore there was no breach of Clause 7.4.

GlaxoSmithKline submitted that throughout her career the representative had undertaken ongoing product and therapy training as set by the company and recently completed the GlaxoSmithKline annual certification test (copy provided), achieving the pass mark of 90% in all 3 therapy areas within which she worked. Over her time at GlaxoSmithKline the representative had undertaken various roles in the company and had never been the subject of an ABPI complaint. Since GlaxoSmithKline maintained that there had been no breach of any clause in the conduct of this representative during the call, and all representative activity was in line with the SPC it submitted that high standards had been maintained at all times by both GlaxoSmithKline and the representative and therefore there was no breach of either Clause 9.1 or 15.2. Furthermore, GlaxoSmithKline provided detailed representative briefing material regarding the licensed indication for Seretide and all representative training included information on the NICE Guideline and the licensed indications for other products used in COPD, and as a result there was no breach of Clause 15.9.

GlaxoSmithKline submitted that it was difficult to comment on the allegation that its representatives in the area had employed a general approach to mislead or present inaccurate information, without details of particular incidents. However, all representatives in the area had been trained and briefed on the same material and would be expected to discuss the same issues in any call with a health professional, ie the respective UK licences for Seretide and Symbicort, the use of Seretide in the treatment pathway of the NICE COPD Guideline and relevant SMC recommendations for use of Seretide in Scotland. There was no attempt by GlaxoSmithKline to mislead any practitioner or make inaccurate representations of licences or guidelines. GlaxoSmithKline was confident that the information presented by the representative in question had been shown to be accurate and in line with both the UK licence and SMC recommendations. Consequently GlaxoSmithKline did not accept any breach of Clause 2 in this regard.

FURTHER COMMENTS FROM THE COMPLAINANT

GlaxoSmithKline's response was sent to the complainant for comment.

The complainant stated that she had been visited by the representative on a few occasions prior to October. However there was only one main meeting which was an introductory meeting where the complainant's role was discussed at length. The purpose of other visits (not meetings) was to drop patient information leaflets, studies and to sign a request for placebo devices (all of which the complainant requested). All meetings and visits were amicable and professional. The use of and licence for Seretide was not discussed until October.

GlaxoSmithKline set up a sponsored meeting (not meetings) to help the complainant network with local practice nurses for which the complainant was very appreciative. She previously enjoyed mutually beneficial relations with pharmaceutical companies and representatives.

The complainant maintained that although the representative distinctly remembered discussing the differences between the UK licences for Seretide and Symbicort in COPD in October, the UK licence was never discussed at this point. The complainant distinctly remembered that only the SMC advice ('licence' was the term the representative used) and the NICE Guideline were discussed (NICE was only discussed because the complainant brought it up). The complainant remembered it clearly as she was taken aback by how aggressively the representative applied her sales pitch. Also, she was always very careful to ensure that representatives supplied evidence to support their claims. The complainant was the only community respiratory nurse specialist in the area and was relied upon to relay accurate information so she could not afford to miss important information or get confused.

The complainant stated there was evidence that she emailed the representative asking her to provide the SMC evidence to support her claim. The complainant did not refer to the NICE Guideline because she had a copy.

It was after this email that the representative telephoned and stated that it was not the SMC but 'whoever' granted the UK licence, the complainant requested a copy. The complainant sensed her anxiety at the complainant following through on her visit and the complainant was then convinced that she had made a deliberate attempt to mislead. The complainant did not discuss this with her.

The SPC and summaries pack was dropped off by the representative who did not stay to review the contents. However, had the complainant known she was going to provide a copy of the SPC the complainant could have saved her the trouble as she already had a copy. As the representative did not stay or follow up with a telephone call she would not have known if the complainant was satisfied.

Even though the claims could not be substantiated the complainant decided that she would speak to the representative and voice her discontent. However, during three education sessions colleagues voiced their surprise at the indications for the use of inhaled corticosteroids (the complainant's presentation contained scans of the SMC, SPC and NICE recommendations for Seretide and Symbicort) and commented that they had been told by a GlaxoSmithKline representative that Seretide could be used after short-acting bronchodilators in the management of COPD. The complainant asked if the representatives had mentioned FEV1 or exacerbations or the NICE Guideline and all said definitely not and realised that this was not an isolated incident and as these individuals did not want to get involved the complainant felt it her duty to make the complaint official.

As for the SMC advice and UK licence for Seretide and Symbicort the complainant was not confused regarding the differences. The complainant agreed that it was entirely appropriate for representatives to discuss the differences between the advice and licence and to discuss Seretide after regular short-acting bronchodilators provided the information was consistent with Clause 3.2 of the Code and did not differ or omit important product characteristics. In this instance the representative had said 'Seretide is licensed by the SMC to use after short-acting bronchodilators'.

The representative completely omitted important particulars listed in the SPC (FEV1 and exacerbations). The statement was economical with the truth and was misleading. It suggested that Seretide could be used if regular short-acting bronchodilators were ineffective regardless of FEV1 and exacerbations. This could result in inappropriate prescription.

Using the word 'licence' instead of advice indicated that it was absolute. Although the SMC advice was important it was only advice.

Mention of the NICE Guideline on COPD should have triggered the representative's memory and at this point she could have mentioned the UK licence and reviewed the small differences between them. The UK licence was never mentioned but instead she insisted that the SMC had 'licensed' Seretide to be used as previously stated. She was so insistent that the complainant doubted herself and that was why the complainant asked for the evidence.

The complainant would have had no problem if the representative had said 'Seretide is licensed to be used after short-acting bronchodilators for patients who have an FEV1 <50% and who have had repeated exacerbations'.

The complainant disagreed with GlaxoSmithKline on the point that the clinical interpretation of the SMC was not out of keeping with the SPC for Seretide. The SMC advice did not mention FEV1 % predicted (just severe disease) or exacerbations.

The complainant did not indicate that the NICE guidance was identical to the SPC, the complainant stated 'in keeping'. The NICE recommendations were only slightly different from the SPC for Seretide. NICE indicated FEV1 <50% and 2 exacerbations in 12 months whereas as the SPC indicated FEV1 <50% and repeated exacerbations.

As for the different patient population the complainant was not sure what was meant. If it referred to the NICE Guideline not being applicable in Scotland then the complainant disagreed. COPD pathology remained the same regardless of country. NHS Quality Improvement Scotland (QIS) usually adopted NICE advice. The local respiratory implementation pack and other documents had been copied from the NICE Guideline. It was a large body of evidence which could not be ignored. Obviously, GlaxoSmithKline agreed with this otherwise NICE recommendations would not be included in its materials.

The complainant did not question the training of the representative or the GlaxoSmithKline training programme. Presumably the inclusion of this section was to provide a character reference. The complainant had been a nurse for 20 years (respiratory specialist for 7 years) and had an excellent professional and academic record. The complainant was not sure that this had any bearing on this complaint.

The complainant stated that she was a plain speaker. This representative flatly denied that she discussed the SMC advice ('licence') so it was her word against the complainant's. The complainant stated she had nothing personal to lose or gain from the complaint and it was made with patients' best interests at heart. The complainant was not under any pressure to meet sales targets in an increasingly competitive market.

The complainant suggested that representatives carried some form of documentation that could be countersigned by the health professional agreeing what was discussed. The complainant did not think it was appropriate that information pertaining to the meeting was entered into a computer without her agreeing the content. The complainant suggested that this was a process open to abuse.

More and more health professionals were refusing to see pharmaceutical representatives and the complainant would be joining them regardless of the outcome of this complaint. This representative's (and other GlaxoSmithKline representatives') conduct had seriously undermined her confidence in the pharmaceutical industry.

The complainant believed that the representative had deliberately misquoted and omitted important information in an attempt to convince her that Seretide could be used earlier than indicated in the SPC. The complainant maintained that she breached the clauses listed in her complaint.

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 the extreme dissatisfaction usually necessary on the part of an individual before he or she was moved to actually submit a complaint.

The Panel noted that the complainant referred to a discussion about SMC recommendations whereas the representative referred to a discussion about the UK licence. Given the complainant's position the Panel queried whether the representative had been sufficiently clear about the differences between Seretide and Symbicort and the differences between the SPC licensed indications and the SMC guidance.

The Panel noted the training material on the SPC for Seretide in COPD stated that Seretide 500 was aimed at patients who had had their second exacerbation. The training material stressed that there were two components to the licence ie FEV1 <50% predicted and that the patients still had symptoms even though they had had regular bronchodialator treatment, either long- or short-acting bronchodilators. The training material also stated that the Symbicort licence was more restrictive than Seretide's COPD licence as patients had to be tried on a long-acting bronchodilator before being put on Symbicort. The Panel queried whether when discussing the differences between the indications for Seretide and Symbicort the representatives were sufficiently clear about the similarities ie FEV1 <50% predicted and a history of repeated exacerbations.

Medicines had to be promoted in accordance with their SPCs. SMC and NICE guidance was occasionally different to the SPC indications.

Clearly it was of concern that the complainant had been taken aback by what she referred to as the representative's aggressive sales pitch and that colleagues had allegedly not been given all the details of the indications for Seretide in COPD. However it was not possible to determine where the truth lay. On the basis of the parties' submissions the Panel did not consider that there was sufficient evidence to show that on the balance of probabilities the representative had promoted Seretide outside its SPC or had failed to maintain a high standard of ethical conduct. The Panel ruled no breach of Clauses 3.2, 7.2, 7.4, 8.2, 9.1 and 15.2. It thus followed that there was no breach of Clause 2.

2 COPD Audit

COMPLAINT

The complainant drew attention to an audit being conducted by GlaxoSmithKline (sample audit report was provided); the report did not reflect the advice given in the NICE Guideline, (2004). The complainant was concerned that patients identified as priority patients (by a practice nurse or GlaxoSmithKline nurse advisor) might be unnecessarily prescribed or switched to Seretide. The complainant alleged a breach of Clauses 18.1 and 18.4.

RESPONSE

GlaxoSmithKline noted that the audit referred to was the part of the review service that was offered by GlaxoSmithKline that had already been the subject of complaint [Cases AUTH/1806/3/06 and AUTH/1809/3/06] and been found not in breach. The audit report provided by the complainant was a summary report of COPD patients for a practice generated by a search of the practice database using software installed by GlaxoSmithKline (Campbell or POINTS) as agreed by the practice. The search generated a report of COPD patients and had two purposes:

- it could highlight areas where the practice might like to improve data recording. For example the audit report provided showed that out of 131 patients, 121 had no record of an MRC dyspnoea score. This might highlight to the practice an area where it could improve patient records so it could better understand the profile of its COPD patients;

- it generated a summary report of priority patients, being those with worse symptoms, exacerbations, hospitalisations etc on which the practice might wish to focus its efforts, eg in a patient review, in order to improve patient care and reduce costs.

GlaxoSmithKline submitted that the database search was carried out after discussion with a non-promotional GlaxoSmithKline representative, the respiratory care associate (RCA). The RCA introduced and explained the GlaxoSmithKline patient review services which included use of software on the practice database to identify priority patients, and use of external health professionals (either local specialists or an agency nurse) to review patients if required by the practice. The practice was free to choose some, all or none of the review services on offer. The database search was the initial part of the review service and identified patients based on a range of criteria which could be seen in the summary report of priority patients. These criteria were: MRC dyspnoea score, FEV1, exacerbations, smoking status, treatment, inhaler technique, admissions oxygen therapy and vaccination. These criteria were set within the installed software but were agreed with and could be adjusted by the practice if required. The audit report was sent to the practice which could act on the results of the report entirely at its own discretion, including no further action, reviewing the patients themselves or engaging further in the GlaxoSmithKline review services by undertaking a specialist notes review or an agency nurse review.

GlaxoSmithKline submitted that the complainant had stated that the audit did not reflect advice given in the NICE Guideline. However, it was difficult to comment without further detail on where the complainant considered the advice was inconsistent since the NICE

Guideline did not state which patients should be identified as a priority. Neither, given the nature of this service and the use to which it was put, would GlaxoSmithKline see an absolute need for the listing to be consistent with the NICE Guideline. The criteria set by GlaxoSmithKline within the search were based on the Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD Guidelines and each search criteria could be referenced to advice recommendations within this initiative. Specifically the GOLD Guideline recommended ongoing monitoring and assessment of patients with COPD and as a part of this advice monitoring of:

- exposure to risk factors (smoking or environmental)
- disease progression and development of complications (symptoms eg dyspnoea and objective measures of lung function eg spirometry)
- pharmacotherapy (including a discussion of current therapeutic regimen and inhaler technique)
- exacerbation history (including severity, frequency and likely causes, as well as hospitalisations).

GlaxoSmithKline noted that the complainant was also concerned that this audit would identify patients that might be unnecessarily prescribed or switched to Seretide. However, it was not the purpose of this audit to identify patients that were suitable for Seretide. This audit report simply identified patients that the practice might want to review, whether it did review the patients or not was entirely up to the practice itself, as no further action was taken by GlaxoSmithKline on the basis of this report other than to provide it to the practice. If the practice wanted to review the patients then it could do this itself, or it could utilise the resources of the GlaxoSmithKline patient review service using a specialist notes review or nurse review service. However, if the patients were reviewed this was done entirely to an agreed practice protocol which might or might not include use of combination treatments and Seretide in particular.

GlaxoSmithKline submitted that as could be seen from the audit report itself, the search simply generated priority patients as described above. In addition, the search also identified patients that were already on combination treatments and did not identify which treatment the patient was on, so of the 16 patients identified as already taking a combination treatment, any or all of them could already be taking Seretide.

Consequently GlaxoSmithKline did not accept any breach of Clause 18.1 and 18.4 in the provision of this audit report as there was no inducement to prescribe, supply, administer, recommend, buy or sell any medicine in this service to medicine which was aimed entirely at enhancing patient care.

PANEL RULING

The Panel noted that in Cases AUTH/1806/3/06 and AUTH/1809/3/06 it had considered a number of nurse audit schemes offered by GlaxoSmithKline including one in COPD. Overall the Panel considered that the services were not unacceptable and were not linked to the prescription of any specific medicine. The decision of what to prescribe lay with the patient's doctor. The services were not an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of Clauses 18.1, 9.1 and 2 of the 2003 Code had been ruled.

Turning to the case now at issue, Case AUTH/1939/1/07 the Panel noted that the complaint related to the failure of material to reflect the NICE Guideline and priority patients might be unnecessarily prescribed or switched to Seretide.

The Panel noted that the Code did not require arrangements for services to necessarily follow NICE guidelines. In general the Panel considered that services etc should not advocate use of medicines in a way that would be inconsistent with their SPCs.

The Panel noted GlaxoSmithKline's submission that the search criteria were agreed with the practice. The criteria were MRC dyspnoea score, FEV1, exacerbations within the last 12 months, smoking status, treatment inhaler technique, admissions, oxygen therapy and vaccination. The purpose of the audit was to identify patients that the practice might want to review. This could be done by the practice itself or using a GlaxoSmithKline service. The GlaxoSmithKline service if used would take place in line with an agreed practice protocol. The search identified patients already on combination treatments without identifying which product the patient was on.

The audit report provided listed 20 priority patients, 16 of whom were currently taking a combination therapy; the report did not identify the patients other than by an identification number nor were details given about which combination therapy patients were on. Of the fifteen patients with a recorded FEV1 result, 14 had an FEV1 <50% of predicted. The number of exacerbations in the last 12 months was noted for each patient and in this regard the audit report took account of the NICE Guideline which, unlike the Seretide SPC, put a time limit on exacerbations. None of the 20 patients had had an exacerbation of their disease in the last 12 months. The Panel queried whether it would be appropriate to prescribe Seretide given the lack of exacerbations within the last 12 months when Seretide's indication, *inter alia*, required patients to have repeated exacerbations.

The Panel considered that on the material before it there was insufficient evidence to show that on the balance of probabilities the audit service was an inducement to prescribe, supply, administer, recommend or buy Seretide. No breach of Clauses 18.1 and 18.4 was ruled.

Complaint received 2 January 2007

Case completed 23 April 2007