CASE AUTH/2017/7/07

ANONYMOUS REPRESENTATIVES v TEVA

Asthma review service

The complainant stated that as a current member of Teva's sales force (s)he was concerned about how representatives were encouraged to achieve their targets for Qvar.

Representatives were asked to sign surgeries up to an asthma review service (the Enhanced Asthma Care Service) provided by an agency, which in turn would find patients suitable to be changed to Qvar. The service was supposed to help practices review their asthma patients and be non-promotional but representatives were increasingly pressurised to sign up at least of six surgeries per year. It was a big issue if representatives fell behind these targets or if the form did not specify a switch to Qvar or Qvar Easi-Breathe.

If the service was purely meant to benefit the practice only, why would the company make such a big deal of setting minimum targets for each representative? The complainant considered the unnecessary pressure coming from the top was being passed on to the customers who might be pushed unethically into something they did not want, by people whose jobs might be at risk if they did not achieve the minimum target.

The Panel noted that supplementary information on switch and therapy review programmes, stated, *inter alia*, that the Code prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine was simply changed to another without clinical assessment. Companies could promote a simple switch from one product to another but not assist in its implementation.

The Panel noted that the complainant was anonymous and noncontactable and thus was cautious when deciding how much weight to attribute to his/her evidence.

The Panel noted from training materials provided by Teva that the objective of the service was to facilitate the systematic identification and review of asthmatic patients in line with BTS/SIGN Guidelines in general practice. The service strategy and rationale in the training pack referred to sub-optimally controlled patients and it was thought that as many as 50% of patients were sub-optimally controlled based on the use of short acting bronchodilators. Teva had decided to sponsor a nurse advisor team to meet this need and review patients in a structured manner. The training materials referred to the Code and clearly stated, *inter alia*, that 'Teva support of a project must NOT be dependent on the customer prescribing a Teva product. This must be neither the fact in practice not the impression given either verbally or in any document connected with the project, internal or external'. It was also noted that the Code prohibited switch services. The introduction of the service authorization form stated that 'This service is provided on the understanding that [GPs] authorizing such services do so on the basis that the services provided are in the best medical interest of their patients and that they, as [GPs], retain complete control of the service at all times'.

The Panel noted that representatives had to introduce the service during a non-promotional call using a service detail aid. The briefing material instructed the representatives to remind the doctor of their previous conversation ie the imminent phase out of Becotide and Becloforte (CFC-containing beclometasone devices. Qvar, Teva's product, was CFC-free beclometasone). It was suggested that the phase out of Becotide and Becloforte be used as the opportunity to review all asthmatics. The representative was instructed to tell the doctor that the service could help: provide a full therapeutic review of all asthmatics; identify controlled asthmatics for a straight change to a CFC-free equivalent for both metered dose inhalers and breath actuated inhalers if required and identify sub-optimally controlled patients for review through a clinic. The briefing material did not mention the BTS/SIGN guidelines. Representatives were briefed to state that the result of the service was that 'CFC transition is implemented for the practice and patient care is optimised for your asthmatic patients'. The service detail aid itself stated that one of the benefits of the service was that it could provide an effective implementation of a CFC-free transition programme. This benefit was, however, listed after other benefits which referred to clinical assessment and the BTS guidelines.

The Panel noted that with poorly controlled asthmatics were defined as those who used an agreed number of short acting bronchodilators over a 12 month period. These people would be sent a symptom questionnaire. The Panel assumed that if patients had used less than the agreed number of short acting bronchodilators over a 12 month period then they would be defined as controlled asthmatics. In this regard, however, the Panel considered that merely noting a patient's use of reliever medication was only a surrogate marker for asthma control. It was possible that some patients who did not use a lot of short acting bronchodilators were nonetheless not optimally controlled. The Panel did not consider such identification on its own constituted clinical review. The Panel noted that nurse advisors would identify all patients that satisfied the review inclusion criteria

that the representatives had discussed and agreed with the lead GP. The instructions to representatives stated that the service design could focus on either patient control and symptoms or CFC transition. The advantages included 'enables practice to complete CFC transition'. The representative's responsibilities with regard to completion of the practice mandate included confirmation of 'which ICS [inhaled corticosteroids] patients were to be reviewed – patients receiving CFC-containing or all patients'. The Panel considered there was a discrepancy within the instructions and with regard to the selection criteria for practices to be offered the service, and queried whether the primary selection criterion really was that they must have key GPs and staff who realised the importance of identifying and reviewing asthma patients who were sub-optimally controlled and should be established on a more effective therapy.

The representatives' training presentation detailed their on-going role once the practice had signed up; this was the start not the end of their role. When scheduling the first date for agency staff to attend the surgery representatives were to make sure that they could be there to *inter alia*, remind the practice of the sponsor and 'Build the relationship three ways'. The representative was to keep in regular contact with the practice. No advice was given in the presentation regarding the relevant clauses of the Code and the limited non-promotional role of the representative once the practice had signed up.

The Panel noted Teva's comments about some PCTs' approach in switching patients from CFC to CFC-free treatment without patient review. It appeared from the materials submitted that it was possible for a practice to use Teva's service for such a switch. Documentation in this regard was included in the Teva service eg the practice treatment mandate. The practice treatment mandate identified five groups of patients: Group 1 was controlled on CFC corticosteroids; Group 2 was controlled on CFC-free corticosteroids; Groups 3 and 4 were sub-optimally controlled either on CFC or CFC-free corticosteroids and Group 5 were non-responders. A template letter, headed 'EACS Immediate Medication Change', was also provided which appeared to indicate that the patient was being switched from CFC to CFC-free without clinical review. The Panel queried why such a template letter was provided at all if practices were chosen because they wanted to identify and review asthma patients who were sub-optimally controlled and establish them on a more effective therapy. A number of items in the training materials referred to the service enabling practices to complete CFC transition. The Panel noted its comments above about the discrepancy between the stated aims of the service and the training and other materials. There were no instructions about what representatives and nurse advisors were to do if all the practice required was a switch from CFC to CFC-free treatment. This was a significant omission.

The Panel had some serious concerns about the arrangements for the service in question and noted that switch services were expressly prohibited under the Code. In this regard the Panel specifically queried the representatives' role in discussing and agreeing inclusion criteria with the GP, the possible inclusion of patients controlled on CFC corticosteroid preparations and the provision of a template 'switch' letter.

In the Panel's view the representatives' briefing material contained mixed messages regarding switch programmes. On one hand representatives were reminded that switch services were prohibited, on the other they were told to 'sell' the services on the basis that, *inter alia*, prescribers could use it to identify controlled patients and do a straight change to a CFC-free beclometasone product (CFC transition appeared to be a greater priority than clinical assessment of patients); template letters for immediate medication change were provided. The Panel considered that the material for the service should have been consistent and made it abundantly clear that switch services without clinical assessment were wholly unacceptable. There should have been no room for doubt. On balance the Panel considered that the representatives' briefing material was ambiguous such that it might be seen by some as advocating a course of action which was likely to lead to a breach of the Code as alleged. In addition and on balance the arrangements for the audit as described in all of the material were unacceptable in relation to the requirements of the Code. Breaches were ruled. The Panel considered that in the conduct of the service, high standards had not been maintained. A breach of the Code was ruled. Given its rulings above the Panel also ruled a breach of Clause 2 of the Code. All but one of these rulings were appealed by Teva.

The Appeal Board acknowledged the clinical value of a review service in asthma given the number of uncontrolled patients and the imminent discontinuation of CFC corticosteroid inhalers. Very many patients even if well controlled, would soon have to be changed over from CFC- containing products to CFC-free alternatives.

The Appeal Board noted that practices were offered the service in question before representatives knew what their prescribing choices would be. In that regard the asthma review service was not linked to the prescription of any medicine. No breach of the Code was ruled.

The Appeal Board, however, noted that a section of the Practice Treatment Mandate which recorded the prescribing decision had to be completed by the Teva representative and the GP. In such circumstances the Appeal Board considered it highly likely that, where such therapy was appropriate, the GP would feel pressurised to specify Qvar. The Appeal Board considered it unacceptable for the representative to be present when the GP recorded his/her prescribing decision and in this regard upheld the Panel's ruling of a breach of the Code.

Notwithstanding its ruling of a breach of a breach of the Code, overall the Appeal Board did not consider

that high standards had not been maintained. No breach of the Code was ruled in that regard. It thus followed that there was no breach of Clause 2 of the Code.

An anonymous representative complained about the promotion of Qvar (CFC-free beclometasome) by Teva UK Limited.

COMPLAINT

The complainant stated that as a current member of Teva's sales force (s)he was concerned about a part of the business which was becoming increasingly pressurised.

The main product promoted was Qvar and representatives obviously had targets which the complainant did not have a problem with. It was how representatives were encouraged to achieve these targets that was worrying.

Representatives were asked to sign surgeries up to a non-promotional asthma review service [the Enhanced Asthma Care Service] provided by an agency, which in turn would find patients suitable to be changed to Qvar. As this was a service that was supposed to help practices review their asthma patients and be non-promotional, it was of concern that representatives were increasingly pressurised to sign up at least of six surgeries per year, which was clearly stated in the representative's mandate. It was a big issue if representatives fell behind these targets or if the form did not clearly specify a switch to Qvar or Qvar Easi-Breathe.

If the service was purely meant to benefit the practice only, why would the company make such a big deal of setting minimum targets to be achieved by each representative? The complainant considered the unnecessary pressure coming from the top was being passed on to the customers who might be pushed unethically into something they did not want, by people whose jobs might be at risk if they did not achieve the minimum target.

The representative stated that (s)he had had to submit this complaint anonymously for fear of reprisal, but (s)he was sure that plenty of evidence would be found in emails, representative mandates etc.

When writing to Teva, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.9, 18.1 and 18.4 of the Code.

RESPONSE

Teva was very surprised and concerned that an employee had complained to the Authority as it had a detailed whistleblower policy which helped and supported employees to alert management to any activities and behaviours they considered improper or unethical. The process was non-judgemental and anonymous. Amongst others it covered a course of conduct which seemed improper for behaviour in Teva or which might compromise or embarrass the representative or Teva, if it were known by co-workers or the public.

The whistleblower policy also stated that an individual should 'Remember that failure to report a violation of the Code is in itself a violation'. Therefore the complainant had failed to follow company procedures.

With regard to this anonymous complaint which suggested increasing pressure in relation to their daily roles and expectations, Teva's response would demonstrate that as a responsible employer it provided objectives in order that an individual's expectations and performance could be assessed in a clearly defined framework. In addition Teva had implemented company wide management processes to help support all staff to help ensure standards and targets in all departments could be achieved.

Teva explained that all employees including sales teams within the pharmaceutical industry were set targets on a number of parameters; including non-sales related activities and therefore it was not unreasonable to set a target in relation to the Enhanced Asthma Care Service. Each representative was required to achieve a baseline of six service implementations per year based on the finite resource. This would ensure that the service was both conducted by nurses that lived throughout the UK and was evenly available to GP surgeries in all regions. It was not unreasonable to expect that targets set for completion in any given year were tracked against performance of all employees within Teva. The sales force was no exception to this.

Teva also noted that as discussed below, the demand for the service outstripped supply and so it was hard to understand the foundation of the complainant's comments about falling behind targets.

Teva would also demonstrate that the service offering complied with the Code. It denied breaches of Clauses 18.4, 18.1, 15.9, 9.1, or 2. The GP practice directed and controlled the service at all times in line with the Data Protection Act 1998.

Representative mandate – meeting the requirements of Clauses 15.9 and 9.1

The mandate clearly set out the focus placed on the representative's different activities. The section on service stated '1.5x surgery referral per quarter from the Enhanced Asthma Care Service'. All relevant sections of the Code were referenced appropriately and clear guidance was outlined eg how representatives were to offer the service. Representatives were told 'Note: You must not discuss any issues relating to Enhanced Asthma Care Service within a promotional sales call. This must be done in a separate service call, on a separate occasion.'

This was a limited resource that was in demand from primary care trusts (PCTs) and health boards and as such it operated on a first come first served basis with representatives. The six per representative per year was indicative of the number each representative could expect to offer if a calculation was made on the number

of nurses employed by the agency, the number of working days in a year, the days on average that the service took to complete divided by the number of representatives.

Teva noted that as from March 2007 it had increased the size of its sales force. Another agency was also appointed to supply a dedicated contract sales team as from March 2007. All representatives had been identically trained. The calculation of the resource available for representatives to offer was based on the number of representatives on territory and the available working days from the agency nurses. Details were provided to support the target of 6 services per year per representative working from 1 January 2007.

Current demand for the service outstripped the available nurse resource, for example one health board had recommended in writing that its 100 practices undertook the service.

Teva believed that its briefing materials were appropriate, fair and clear. Teva clearly positioned the nurse service within these briefing materials as providing a service to medicine that was non-promotional.

Teva did not understand why a sales person should be worried about achieving targets as it was a key measure of any sales or commercial position in any industry.

Enhanced Asthma Care Service – meeting the requirements of Clauses 18.1 and 18.4

Service rationale and aims

Asthma was one of the most common and treatable conditions affecting patients in the UK. Asthma UK quoted the following statistics:

- 1 in 12 adults had asthma
- 1 in 10 children had asthma
- The UK had one of the highest rates of people with asthma of any country in the world
- 1,400 died of asthma each year in the UK.

Whilst the number of deaths was small compared to heart disease and cancer the difference was that it was believed that up to 90% of these deaths were preventable (Asthma UK) if practices managed patients in line with the BTS/SIGN (British Thoracic Society/Scottish Intercollegiate Guidelines Network) guidelines.

This was well recognised by opinion leaders in this area and a leading expert – a consultant chest physician and former chair of the BTS Standards of Care Committee – had stated that 'asthma can be very successfully treated by health professionals if time was applied and BTS/SIGN guidelines were followed. Asthma can be adequately controlled if a patient is prescribed the correct medicine, with an adequate management plan. Hospital admissions could be reduced and quality of life improved if patients took their treatment and were given correct advice'.

Unfortunately whilst asthma care was far from optimum as demonstrated by the above statistics its successful management was well down the list of NHS priorities and this was reflected in the fact that it was given little prominence within the GMS contract. The service had been designed to help put asthma back on the NHS agenda by raising the awareness that 'asthma is not sorted' and that the BTS/SIGN guidelines provided the framework for successful management. The service was a full BTS/SIGN implementation service that provided additional resources (specialist asthma nurses) to help deliver improved patient outcomes. The service has been requested by strategic health authorities, health boards, PCTs and many individual practices for that purpose.

For the patient the service aimed to achieve a level of asthma symptom control that allowed them to lead a normal life and to minimise exacerbations with minimal side-effects.

For the practice the service aimed to: ensure the patient received the optimum treatment in line with the practice protocol; implement interventions after review which would aim to improve patient outcomes and provide a service to patients in line with the BTS/SIGN guidelines together with the clinical governance agenda.

The service was undertaken for the benefit of the NHS and was in the best interests of the patient.

Practice recruitment and the authorization process

The service provided a full therapeutic review for the practice; it was introduced in detail to the practice by the Teva representative in a non-promotional call. In some instances the Teva representative might have delivered a brief description of the service during a promotional call and delivered the approved bridging item prior to the non-promotional call. The Teva representative was responsible for ensuring that the practice completed the authorization form.

Completion of the service authorization form

Practices interested in undertaking the service completed sections 1 and 2 of the service authorization form which included the practice treatment mandate prior to the engagement of the service provider.

The authorization form permitted the practice to define which asthmatics it wished to review and to agree a course of action to follow for each patient group at each step of the guidelines.

At least two GP signatories (ideally all partners) was required. In a single handed practice, one GP signature supported by the signature of the practice nurse or manager would be sufficient. The GP signatories stated that they were authorized to sign on behalf of the practice and undertook to accept full responsibility for communicating the activities contained therein to all members of the practice whom the service activities would affect. A lead GP for the service was nominated who would be responsible for liaising with the agency

nurse and practice staff to ensure the smooth implementation of the service.

Patients included in the asthma review

Within the authorization form the practice could decide whether to review asthma patients on all types of inhaler or just those on specific types of devices depending on practice requirements. All inhaler device types available were given on the authorization form. The lead GP for the service authorized the practice decision.

Practice treatment mandate

The service process was then discussed with the GP after which the practice completed the Practice Treatment Mandate and authorized the practice requirements.

For the purposes of service delivery patients were split into controlled and sub-optimally controlled patient groups.

Sub-optimally controlled patients were defined as those who had had an agreed number of short-acting bronchodilator (SAB) inhalers over the previous 12 month period. An over-reliance on SAB inhalers, which were used for symptomatic relief, indicated that the patient needed further investigation as recognised in the BTS/SIGN guidelines.

Patients defined by the practice as sub-optimally controlled were sent a symptom questionnaire. This established if they had experienced asthma symptoms in the last month which either affected their ability to sleep, affected them during the day or interfered with their ability to undertake normal activities.

The Practice Treatment Mandate allowed the practice to define a course of action for all possible patient groups:

- Patients on CFC containing corticosteroids who were controlled (in line with practice definitions)
- Patients on CFC containing corticosteroids who were sub-optimally controlled
- Patients on CFC free corticosteroids who were controlled
- Patients on CFC free corticosteroids who were sub-optimally controlled
- Non responders to symptom questionnaires.

This represented the majority of asthma patients, however patients on combination therapies and other additive therapies were all included in the review and presented as controlled/uncontrolled in line with the number of SABs set by the practice. Dependent on the protocol being implemented there might be both step down and step up actions being implemented by the agency nurse advisor.

The practice might decide to define a range of treatment options for each patient group which following a full therapeutic review might include being invited to a clinic, medicine changes, no action or an alternative course of action that the practice would like to follow.

All prescribing decisions for each patient group were made by the practice prior to the engagement of the agency. The agency implemented the BTS/SIGN guidelines utilising the practice protocol.

Finally, prior to contacting the agency to implement the service the lead GP signed the authorization form.

Scheduling the event

The agency had a dedicated service scheduling line which practices could call after completing the authorization form in order to book a specialist asthma nurse to implement the practice protocol. The signed authorization form was then sent to the agency for forwarding to the allocated nurse.

Service implementation stage by stage

The overall service structure was given in the service authorization form:

Service overview

The support provided by the agency following the completion of the authorization form was in three stages as detailed below. The service took approximately four days (including two clinic days) to deliver in an average three GP practice.

Service stages in detail

1 Patient identification

Agency nurse advisors identified all patients that satisfied the review inclusion criteria set by the practice in the authorization form. Following identification of the patients the nurse advisor would produce the template letter, approved by the GP at their initial meeting, to accompany the patient engagement material (including symptom questionnaire) that would be sent to all patients that satisfied the practice's inclusion criteria.

2 Patient review

Responses from the questionnaire were incorporated into a practice baseline report which would include information on all asthma patients in the practice.

Nurse advisors could not and would not discuss or recommend any specific therapy choices, but in line with their duty of care they would question GPs who appeared reluctant to fulfil their obligations to review patients who, in the nurse's professional opinion might require additional support and care.

If, after the presentation of patient summaries, the GP wished to implement any actions with any patient in order to fulfil the guidance laid down by the BTS/SIGN guidelines – for instance medicine upgrade or invitation to a consultation, the nurse advisor would implement the written instructions given by the GP

prior to leaving the practice. The GP might decide to take no action because the treatment was considered to be suitable.

The nurse advisor would also let the practice know about those patients who did not respond to the questionnaire and who might therefore require an alternative approach and those patients whose treatment fell outside of the BTS/SIGN guidelines with a recommendation that the practice bring these patients in for review.

3 Clinic review

Patients who the GP considered would benefit from a clinic review were invited to attend and counselled in accordance with the clinic mandate that the nurse advisor would discuss with the practice if a patient required step up/step down intervention.

Clinics could be carried out either by an agency nurse advisor or the practice nurse as required by the practice.

The agency nurse advisor could advise to the practice nurse on how to deliver respiratory review clinics that would be of long term benefit to the practice and their patients.

Details of what took place in the clinic were as follows:

The agency nurse advisor would advise on how the practice had decided to treat its respiratory patients. If the medicine needed to be changed as per the practice protocol, the nurse would tell the patient of the proposed new medicine and provide guidance on inhaler technique. If the patient only needed counselling this would be provided in accordance with the practice protocol.

A detailed summary sheet for each patient consultation would be presented to the lead GP. The GP would then authorize the action proposed by the agency nurse advisor in alignment with the protocol eg a medicine change or other intervention, or an acknowledgment that the patient's status was acceptable.

For all interventions authorized by the practice, the agency nurse advisor or practice nurse would update the patients' records. In addition, the patient's GMS asthma template would be updated to capture the findings of the review. A letter informing the patient of this would be produced by the nurse advisor and left with the practice for posting.

At the end of clinic days the agency nurse advisor would transmit the patient anonymised data relating to the clinic activity to the agency head office.

At the completion of the service to a practice, a report detailing respiratory patient caseload status and actions undertaken would be left with the practice. It was anticipated that the report would be of value when the practice reviewed its delivery of GMS Quality Outcome Framework key indicators and demonstrated that it had undertaken a review to improve quality of care. A sample practice report was included in the representative training folder.

A practice folder was created by the nurse advisor at the start of the service into which a constantly updated copy of the authorization form was inserted along with hard copies of signed/approved template letters, authorized course of action sheets (individual GP signatures against each patient for medicine changes) and a CD containing all search data and baseline information. This folder was the practice's permanent record of every action undertaken to implement the BTS/SIGN guidelines within the practice.

The service implemented a full therapeutic review in line with the BTS/Sign guidelines for the practice. The practice defined which patients were to be reviewed the treatment mandate for each patient at all steps of the BTS/SIGN guidelines and the practice explicitly authorized any intervention for patients that met the practice mandate.

The service used agency asthma nurse specialists to 'kick start' the patient review process and implementation of the BTS/SIGN guidelines which the practice would continue following the completion of the service. The result was that the BTS/SIGN guidelines were implemented for all asthma patients in participating practices.

Representative materials related to service delivery

All representatives recruiting practices to undertake the service were trained by the agency for at least one day at the earliest opportunity. As part of the service training the agency also briefed the representative on the ABPI guidelines in relation to the provision of added value services. A representative questionnaire together with an examination and sample answer set was included in the representative's training folder.

All materials used to promote the service to health professionals clearly stated that the service was sponsored by Teva as a service to medicine ie they carried corporate branding only. All service materials sent to patients ie questionnaires and patient letters carried corporate branding only, ie included the banner 'sponsored by Teva UK Limited as a service to medicine'. Before being sent the patient letters might be modified by the GP to meet practice requirements as long as changes requested met the Code.

Patients were sent a description of the service and could opt out if they did not want a third party review of their asthma care or if they would not like a mandated medicine change to occur.

The service introduction within the representative's folder was introduced in recognition that many PCTs advocated the 'switch' from CFC formulations to CFC-free formulations without patient review. This was not in the best interest of the patient and was not advocated by the General Practitioners in Asthma Group – it recognised that the CFC transition provided an opportunity to improve asthma care by the systematic review of patients and encouraged a

managed transition which was in the best interest of the patient. Whilst the service could be used to implement the CFC transition this briefing material was provided to advocate that a 'switch' was not what the service was about. It was the patient's asthma control that was important, just because a patient was or was not on a CFC-free aerosol did not necessarily mean that they would be controlled. Whilst practices might find that the service was a useful platform to allow them to implement a CFC transition in selected patient groups, it was the view of the agency that patients should have their asthma control assessed prior to any CFC transition and symptomatic patients reviewed through clinics. Whilst a 'switch' was being advocated by many PCTs the service advocated against 'switch' and endorsed a full therapy review be conducted prior to the course of action being decided for an individual patient.

Staff working on the service

Teva provided copies of the internal briefing material for the agency nurse advisor team. Its team was passionate about optimising asthma care and was motivated by a desire to implement the practice treatment mandates of participating practices in order to 'make a difference'.

As of 30 June all nurses working full-time on this project possessed an asthma diploma or higher qualification. Teva provided the credentials of its team by way of thumb-nail CVs. Prior to their employment at the agency many of the staff worked on PCT projects relating to respiratory medicine. Recently one of the team had won a prestigious national award in recognition of innovative work in respiratory medicine.

All the nurses undertook a thorough month's training course and were trained and validated both in the classroom and in the practice environment before being sent to a practice on their own. Nurses also had to pass a written exam to demonstrate knowledge of the service before being deployed in the field.

In addition to the initial training each team member was visited once per month and their performance assessed to ensure high quality standards were addressed.

Service reports

The practice received a completion report in relation to service outcomes as outlined in the service authorization form.

When implementing the service no patient identifiable information was removed from the practice. The only information removed from the practice was an anonymised outcome report containing statistical information relating to service implementation. Before the service started the doctor signed the service authorization in order to confirm that they had read, understood and agreed with content. This section explained that the agency complied with the Data Protection Act 1998 and followed all legislation in relation to the protection of patient confidentiality. It also stated that GPs authorizing the service did so on the basis that the services provided were in the best medical interest of their patients.

In addition, on completion of the service, the authorization form was signed by the practice. This allowed the agency to give summary data about the service to Teva; no patient identifiable information was given to the company. If the practice did not sign this section then no information about the service was sent to Teva. The authorization form stated that the agency would not disclose any personal data to any third party in any circumstances except at the written request of the GP.

Contractual remunerations

The agency was paid a flat fee per nurse deployed on the project. There were no performance related bonuses paid to the agency by Teva as a direct result of the contract.

There were no incentive schemes linked to Teva product sales included in the contract or sales force performance included in the contract.

Teva provided details of the key performance indicators included within the contract and of how the service quality was assessed.

Nurses attached to the service could earn an annual bonus related to the implementation of the therapeutic review. Details were provided

Summary of compliance with Clauses 18.1 and 18.4

Teva submitted that the facts presented below when overlaid with the comprehensive description of the service above, together with the service materials provided, demonstrated that the company had complied with Clauses 18.1 and 18.4.

Clause 18.1

- 1,400 people died unnecessarily from asthma each year
- Around 90% of these deaths were preventable by better patient management
- This was well recognised by opinion leaders in this area one of whom had stated that 'asthma could be very successfully treated by health professionals if time was applied and BTS/SIGN guidelines were followed'
- The service was a full BTS/SIGN implementation service
- GPs authorizing the service explicitly signed the service authorization form to agree that they believed the EACS service was in the best medical interests of their patients
- A national opinion leader had also stated that if the BTS/SIGN guidelines were implemented 'hospital admissions could be reduced and quality of life improved if patients took their treatment and were given correct advice'. This was clearly in the best interests of patients and the NHS
- No gift, benefit in kind or pecuniary advantage

was offered in relation to the service to health professionals as an inducement to prescribe, supply, administer, recommend or buy or sell any medicine. The fact was that GPs undertaking the service must invest practice time in order to implement it, take time to agree a practice protocol and authorize each and every step of the service together with authorizing any individual patient intervention. Practice prescribing costs might increase or decrease depending on individual practice treatment mandates. Practices within their treatment mandate would decide which asthma patients to review and a course of action for each individual patient which might or might not include medical interventions. The service was a full BTS/SIGN implementation service which would help reduce hospital admissions, reduce exacerbations, reduce hospital admissions and might even prevent some unnecessary asthma deaths.

Clause 18.4

- As outlined above GPs authorizing the service explicitly signed the service authorization form to agree that they believed the service was in the best medical interests of their patients
- A national opinion leader had stated that if the BTS/SIGN guidelines were implemented 'hospital admissions could be reduced and quality of life improved if patients took their treatment and were given correct advice'. This was clearly in the best interests of patients and the NHS
- The service contained corporate branding and was clearly displayed on all service materials used with health professionals and/or practice administrative staff
- The involvement of Teva in the therapy review service was made clear to all patients. All patient engagement materials clearly stated that the service was sponsored by Teva, a pharmaceutical company which manufactured medicines for the treatment of asthma. In addition all letters sent to patients contained the same banner. Finally patients reviewed by agency nurse advisors through clinics signed the clinic assessment sheet (contained within the service authorization form) giving their expressed consent for the nurse from an outside agency to review their asthma medicine and current management
- The service was discussed in detail by the Teva representative with practices that had expressed interest in a non-promotional call. In some instance the representative would leave the service bridging piece/leavepiece about the service in a promotional call but would not instigate a detailed discussion of the service at that time
- The service provider was a sponsored registered nurse who held an asthma diploma or a higher qualification. All nurses received training in relation to the Code and the Data Protection Act 1998 as part of their initial training course before they undertook any practice activity
- No patient identifiable information was provided to Teva or any of its representatives as part of service delivery
- The nurse team was not involved in the promotion of a product in any way. The recommendation or promotion of a product by any agency nurse would constitute a breach of Teva's disciplinary process and if proven would result in gross misconduct and instant dismissal
- Contractual payments in relation to payment for the service were not linked to sales in any way. There were no performance related payments in the contract that would be payable to the service provider. The only bonus provisions related to nurse payments and was based around interventions contained within the BTS/SIGN guidelines. The service had not been designed as an audit but rather an implementation package whereby interventions were undertaken (decided by the practice within the treatment mandate) for patients who were sub-optimally controlled (the definition of sub-optimally controlled being defined by the practice) in order to optimise patient asthma outcomes. Medical and non-medical options were defined as an intervention ie there was no direction given in favour of for example a medical intervention; patient education might provide the best outcome for a patient. The nurses simply implemented what the practice dictated
- The agency operated within the framework of the detailed written instructions contained within the nurse briefing packs. This was compiled jointly between the agency and Teva and represented the operational requirements to which the agency must deliver. This pack also contained guidelines in relation to patient confidentiality and did not advocate either directly or indirectly any course of action that would be likely to lead to a breach of the Code
- Practices contacted the agency to book the service, the agency did not contact the practice. If the agency telephoned the practice for any reason the caller stated that they were from the agency which implemented the Teva sponsored service
- The practice completed the practice treatment mandate on the service authorization form prior to the engagement of the agency. Therefore when the agency staff first entered a practice they were there to implement the treatment mandate already produced by the practice. Written updates in relation the implementation were kept current and left in a practice folder. The identity of the sponsoring company was given on the authorization form that contained the treatment mandate completed by the practice. All data removed from the practice was documented on the service authorization form and the use to which that data was put. Expressed consent was gained

from the practice for such data to be removed from the practice

- All service material was non-promotional and identified the sponsoring company. The material did not comment on any competitor to Teva.

- All service materials were certified by Teva's Code of Practice signatories.

- The service was discussed with NHS trusts, health authorities, health boards and PCTs on a pro-active basis. Indeed there had been a high degree of interest and many organisations had recognised that the treatment of their asthma patients was sub-optimal. This had resulted in some organisations recommending the service to all of its practices. A BTS/SIGN guidelines service was likely to be cost neutral in relation to budgetary implications. Budgetary savings might be made in relation to hospital admissions that were in the best interest of the NHS

- The service was not a 'switch' service. The service was a full therapeutic review that assisted practices by conducting a clinical assessment of their patients and implementing the practices treatment mandate in line with the BTS/SIGN guidelines.

The service did not change patients' medicine without a clinical assessment.

Outcomes following the therapy review for individual patients might be/and were: no change; change of medicine/ device; stop medicine; change dose; patient education or addition of a spacer device.

The practice decided which interventions it believed were most appropriate for each individual patient and were documented as such. Medical and non-medical interventions were included and the product choice was not limited to those of Teva. All service documentation capturing individual interventions was left with the practice following completion of the service.

Representative mandate – meeting the requirements of Clause 9.1

Pharmaceutical sales teams were set targets on a number of parameters, including non-sales related activities; therefore it was not unreasonable to set a target in relation to the service. The target of six/representatives/year was appropriate as detailed above. It was not unreasonable to expect that targets were tracked against performance.

Teva noted that some PCTs independently recommended the service as they clearly saw the benefit to GP practices and patients alike.

The service - meeting the requirements of Clause 9.1

The practice treatment mandate was filled in by the GP authorized to do so. The practice controlled all prescribing decisions, authorizing individual medicine changes if required. The GP therefore made all decisions relating to the prescription of medicine and Teva had no input into this process. The practice was in complete control of the whole process, any decision the practice made would be implemented under the remit of the service by the agency nurse advisor.

Representative mandate – meeting the requirements of Clauses 9.1 and 2

In relation to the setting of targets, Teva noted its comments above

Teva emphasised the following in relation to the complainant's comment on '…unethically pushed…'. The practice treatment mandate was filled in by the GP or GPs authorized to do so. The practice controlled all prescribing decisions, authorizing individual medicine changes if required. The practice was in complete control of the whole process, any decision the practice made would be implemented under the remit of the service by the agency nurse advisor.

Teva believed this was a valuable independent nurse-led service that was widely accepted by doctors and primary care organizations. Teva did not believe that any health professional would sign up to the service if they did not think it was in the best interests of the practice and its asthma patients.

Internal procedures – meeting the requirements of Clauses 9.1 and 2

Teva and any contracted third party suppliers had extensive policies and procedures in place regarding grievance and business ethics. The quotes below came directly from Teva's Code of conduct.

'For Teva, it is very important to succeed, but in a single way: honestly and fairly, both from the standpoint of work relations between employees within the company and in its relations with external customers, suppliers and shareholders. The ethical behavior and integrity of Teva's people worldwide have always been an integral part of Teva's culture – the Teva Way.'

This encompassed, *inter alia*, conduct which:

- in the employee's knowledge or opinion, was illegal

- contradicted the guidelines set out in Teva's Code of Business Conduct and/or contradicted company policies and procedures

- seemed improper for behavior in Teva

- might compromise or embarrass the employee or Teva, if it were known by co-workers or the public.

It went on to explain the 'Whistleblower' procedure put in place to assist and support employees who believed that Teva's Code of Conduct might have been breached. It explained, *inter alia*, that:

- The role of Teva's audit committee in regard to the whistleblower procedures was to examine complaints and suspicions and, when necessary, to investigate

- When reporting anonymously through the 'confidential hotline', sufficient details should be provided to enable examination of the complaint (such as dates, description of events etc)

- Protection of employees – the audit committee would not reveal the identity of the person who had made the report and would not tolerate any retaliation against anyone who reported irregularities

- Those found to be in violation of this Code were subject to appropriate disciplinary action, up to and including termination of employment. Criminal misconduct might be referred to the appropriate legal authorities for prosecution.

All Teva employees attended a human resources workshop or completed an online presentation on business ethics during 2006. This was part of the induction process for all new employees.

The sales agency as a contracted third party sales force supplier also had clear guidelines on business ethics. All employees received a copy of the business ethics leaflet with their contract of employment and any employees who were with the agency at the end of 2006 also received a copy. There was a slide on business ethics and the reporting process at the company induction.

Teva and the agency had appropriate internal procedures in place to deal with complaints of this nature. Neither company had received an internal complaint via either of Teva's clearly defined anonymous internal complaint procedures on this matter from a current employee.

Additional Information

Training

Representative training ABPI – meeting the requirements of Clauses 15.9 and 9.1

All representatives were, *inter alia*, provided with a copy of the Code on their initial training courses. They had returned signed declarations that they had received and had read and understood their obligations under the Code.

The representative mandates referred to these documents appropriately.

Representative training and audit– meeting the requirements of Clauses 15.9 and 9.1
All representatives were trained on the agency nurse service offering and had a copy of the training manual and were checked on their competence to implement the service.

All training materials had been appropriately certified in line with Clause 15.9.

PANEL RULING

The Panel noted that the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated, *inter alia*, that Clauses 18.1 and 18.4 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine was simply changed to another without clinical assessment. Companies could promote a simple switch from one product to another but not assist in the implementation of it.

The Panel noted the complainant's comments. The Panel also noted that the complainant was anonymous and noncontactable and thus was cautious when deciding how much weight to attribute to his/her evidence.

The Panel noted that Teva had provided the training materials for the representatives and for the agency nurse advisors. The material stated that the objective of the service in question was to provide GPs with a facilitation platform for the systematic identification and review of asthmatic patients in line with BTS/SIGN Guidelines. The service strategy and rationale in the training pack referred to sub-otimally controlled patients and it was thought that as many as 50% of patients were sub-optimally controlled based on the use of short acting bronchodilators. Teva had decided to sponsor a nurse advisor team to meet this need and review patients in a structured manner. The training materials referred to Clauses 18.1 and 18.4 of the Code and clearly stated, *inter alia*, that 'Teva support of a project must NOT be dependent on the customer prescribing a Teva product. This must be neither the fact in practice not the impression given either verbally or in any document connected with the project, internal or external'. It was also noted that Clause 18.4 of the Code prohibited switch services. Section 3A of the service authorization form stated in its introduction that 'This service is provided on the understanding that [GPs] authorizing such services do so on the basis that the services provided are in the best medical interest of their patients and that they, as [GPs], retain complete control of the service at all times'.

The Panel noted that representatives had to introduce the service during a non-promotional call using a service detail aid. The briefing material instructed the representatives to remind the doctor of their previous conversation ie the imminent phase out of Becotide and Becloforte (CFC-containing beclometasone devices. Qvar, Teva's product was CFC-free beclomethasone). It was suggested that the phase out of Becotide and Becloforte be used as the opportunity to review all asthmatics. The representative was instructed to tell the doctor that the service could help him: provide a full therapeutic review of all asthmatics; identify controlled asthmatics for a straight change to a CFC-free equivalent for both metered dose inhalers and breath actuated inhalers if required and identify sub-optimally controlled patients for review through a

clinic. The briefing material did not mention the BTS/SIGN guidelines. Representatives were briefed to state that the result of the service was that 'CFC transition is implemented for the practice and patient care is optimised for your asthmatic patients'. The service detail aid itself stated that one of the benefits of the service was that it could provide an effective implementation of a CFC-free transition programme. This benefit was, however, listed after other benefits which referred to clinical assessment and the BTS guidelines.

The Panel noted that with regard to patient identification, poorly controlled asthmatics were defined as those who used an agreed number of short acting bronchodilators over a 12 month period. These people would be sent a symptom questionnaire. The Panel assumed that if patients had used less than the agreed number of short acting bronchodilators over a 12 month period then they would be defined as controlled asthmatics. In this regard, however, the Panel considered that merely noting a patient's use of reliever medication was only a surrogate marker for asthma control. It was possible that some patients who did not use a lot of short acting bronchodilators were nonetheless not optimally controlled. The Panel did not consider such identification on its own constituted clinical review.

The Panel noted that it was stated that the nurse advisors would identify all patients that satisfied the review inclusion criteria that the representatives had discussed and agreed with the lead GP in the practice. The instructions to representatives stated that the service design could focus on either patient control and symptoms or CFC transition. The advantages included 'enables practice to complete CFC transition'. The representative's responsibilities with regard to completion of the practice mandate included confirmation of 'which ICS [inhaled corticosteroids] patients were to be reviewed – patients receiving CFC-containing or all patients'. The Panel considered there was a discrepancy within the instructions and with regard to the selection criteria for practices to be offered the service, and queried whether the primary selection criterion really was that they must have key GPs and staff who realised the importance of identifying and reviewing asthma patients who were sub-optimally controlled and should be established on a more effective therapy.

The representatives' training presentation detailed the representatives' on-going role once the practice had signed up to the programme and they were told that this was the start not the end of their role. When scheduling the first date for agency staff to attend the surgery representatives were to make sure that they could be there to *inter alia*, remind the practice of the sponsor and 'Build the relationship three ways'. The representative was to keep in regular contact with the practice. No advice was given in the presentation regarding the relevant clauses of the Code and the limited non-promotional role of the representative once the practice had signed up.

The Panel noted Teva's comments about some PCTs' approach in switching patients from CFC to CFC-free treatment without patient review. It appeared from the materials submitted that it was possible for a practice to decide to use the Teva service for such a switch. Documentation in this regard was included in the Teva service eg the practice treatment mandate. The practice treatment mandate identified five groups of patients: Group 1 was controlled on CFC corticosteroids; Group 2 was controlled on CFC-free corticosteroids; Groups 3 and 4 were sub-optimally controlled either on CFC or CFC-free corticosteroids and Group 5 were non-responders. A template letter, headed 'EACS Immediate Medication Change', was also provided which appeared to indicate that the patient was being switched from CFC to CFC-free without clinical review. The Panel queried why such a template letter was provided at all if practices were chosen because they wanted to identify and review asthma patients who were sub-optimally controlled and establish them on a more effective therapy. A number of items in the training materials referred to the service enabling practices to complete CFC transition. The Panel noted its comments above about the discrepancy between the stated aims of the service and the training and other materials. There were no instructions about what representatives and nurse advisors were to do if all the practice required was a switch from CFC to CFC-free treatment. This was a significant omission.

The Panel had some serious concerns about the arrangements for the service in question and noted that switch services were expressly prohibited under the Code. In this regard the Panel specifically queried the representatives' role in discussing and agreeing inclusion criteria with the GP, the possible inclusion of patients controlled on CFC corticosteroid preparations and the provision of a template 'switch' letter. The Panel noted the complainant's concern that representatives had to sign up six surgeries per year and that it was a 'big issue' if these targets were not met or if the form did not specify a switch to Qvar.

In the Panel's view the representatives' briefing material contained mixed messages regarding switch programmes. On one hand representatives were reminded that switch services were prohibited, on the other they were told to 'sell' the services on the basis that, *inter alia*, prescribers could use it to identify controlled patients and do a straight change to a CFC-free beclomethasone product (CFC transition appeared to be a greater priority than clinical assessment of patients); template letters for immediate medication change were provided. The Panel considered that the material for the service should have been consistent and made it abundantly clear that switch services without clinical assessment were wholly unacceptable. There should have been no room for doubt. On balance the Panel considered that the representatives' briefing material was ambiguous such that it might be seen by some as advocating a course of action which was likely to lead to a breach of the Code as alleged. In addition and on balance the arrangements for the audit as described in all of the material were unacceptable in relation to the requirements of Clauses 18.1 and 18.4. Breaches of Clauses 15.9, 18.1 and 18.4 were ruled. The Panel considered that in the conduct of the service,

high standards had not been maintained. A breach of Clause 9.1 was ruled. Given its rulings above the Panel also ruled a breach of Clause 2 of the Code. These rulings were appealed by Teva except the Panel's ruling of a breach of Clause 15.9 which was accepted.

The Panel then considered whether the circumstances were such that a formal report under Paragraph 8.2 of the Constitution and Procedure should be made to the Code of Practice Appeal Board. The Panel decided not to make such a report as there was clinical review for uncontrolled patients and some element of review to establish which patients were controlled. Some of the instructions referred to the requirements of Clauses 18.1 and 18.4 and their supplementary information.

APPEAL BY TEVA

Teva appealed the Panel's rulings of breaches of Clauses 2, 9.1, 18.1 and 18.4; it was very concerned that sections in the ruling appeared to be contradictory or inaccurate.

Teva accepted that some of the internal briefing materials could have discussed the implementation of the service in more detail and contained statements that could be misinterpreted but it did not accept that the asthma review programme was a switch programme. Teva was however conscious that as it was a very detailed and complex service and it had therefore had to submit a large volume of documents in its response which had made it an enormous task for the Panel to conduct a detailed review.

Teva noted that the Panel had not made a report to the Appeal Board under Paragraph 8.2 of the Constitution and Procedure as there was clinical review for uncontrolled patients.

Teva submitted that this was contradictory as for controlled patients the ruling stated that the Panel assumed that if patients had used less than the agreed number of short acting bronchodilators (SABs) over a 12 month period that they would be defined as controlled asthmatics. In this regard, however, the Panel considered that merely noting the patient's use of reliever medication was only a surrogate marker for asthma control. The Panel did not consider such identification on its own constituted clinical review.

An identical data set was collected as part of a full clinical assessment for all asthma patients within participating practices, ie for both controlled (defined as SAB use above an agreed level over the previous 12 months) and uncontrolled patients. This data set which could be seen within section 7 of the representative's manual comprised an additional 76 data sets (in addition to SAB use) that were collected for all patients as part of the clinical assessment and constituted the 'electronic baseline assessment'.

- Therefore the only action that was different for controlled and uncontrolled patients was that uncontrolled patients received a symptom questionnaire but controlled patients did not require one as they had a low level of SAB use (defined by the practice) and no asthma symptoms in the GP notes. If the practice wished to send all asthma patients a symptom questionnaire, then this could be stated on the authorization form and would be implemented by the agency if required.

- The 'electronic baseline assessment' was then presented to the practice. All 77 collected data sets relating to patients were then reviewed on an individual basis by the nurse and the GP in order for the GP to decide a course of action. This could clearly be seen on the authorization form. Even if a patient used a low number of reliever inhalers, if that patient had other treatment issues, eg admission to hospital with an asthma attack, then the practice might decide that the patient was not controlled and treat the patient accordingly. Reliever use was only used as an initial marker for asthma control. The use of reliever inhalers was a marker advocated by the BTS. In other words every patient received a full clinical review before the GP authorized a specific course of action and reliever use alone was not used to agree a course of action for an individual patient.

Controlled patients were therefore treated in exactly the same way as uncontrolled patients, the same data sets were collected from both groups of patients and no action was taken for any patient without a full clinical review with the GP.

Given the above, Teva asked why the Panel had ruled on controlled and uncontrolled patients in a very different manner and the reasoning given as both groups had been enrolled and reviewed by the GP by the same process? Why had the Panel viewed the service as a 'switch service'?

Actions taken in relation to sales force materials

Teva noted that the Panel, on balance, considered that the representatives' briefing material was ambiguous such that it might be seen by some as advocating a course of action which was likely to lead to a breach of the Code as alleged. Teva accepted this finding and had withdrawn all service materials from the sales force. The sales force was re-briefed (26 September) so there could be no misunderstanding that all company employees must adhere to the Code and briefing materials were being rewritten to ensure that there were no statements that could be considered as ambiguous. It was clearly stated that the service was a full asthma review service and not a switch service. The sales force materials now ensured that there was no possible ambiguity before they were re-issued.

Clauses 18.1 and 18.4

Teva submitted that in terms of the sales force materials, these were being amended as outlined above in order to comply with Clauses 18.1 and 18.4.

Enhanced Asthma Care Service

Teva disagreed that this service represented a switch service, thus ultimately breaching Clause 2 (as well as

Clauses 9.1, 18.1 and 18.4) and it therefore appealed against this ruling but it required clarification as stated above relating to controlled and uncontrolled patients to make an effective response. However, Teva understood the Panel's concerns and it had therefore taken the following immediate actions to implement changes prior to the appeal:

- Service recruitment was suspended on 25 September 2007
- All materials were withdrawn verbally from the sales force on 26 September at the re-briefing and by email on 1 October 2007
- All documents related to the service were now subject to review prior to appeal to ensure complete compliance with the Code.

Teva submitted that a large part of the Panel's ruling was based on the lack of a full clinical review for controlled patients. This was clearly factually incorrect as outlined above.

When it provided its reasons for its appeal Teva noted its regret that its request for clarification on the ruling had been refused as it would have aided it greatly in constructing its appeal. Teva submitted that the service greatly benefited the NHS and ultimately patients.

Teva reassured the Panel that it was committed to the Code and it had robust procedures in place to ensure compliance. The Panel's ruling contained statements that appeared to be factually incorrect. It appeared that sections of the ruling were based on assumptions that could not be substantiated from either the documents it submitted, or from the anonymous complaint. Furthermore Teva noted that the Panel had changed the words from how they appeared within some of its service materials within its ruling. This potentially questioned the basis of the ruling.

Teva requested that each member of the Appeal Board was provided with a full set of all the documents submitted in relation to this case together with the supporting CD. Importantly the CD contained a mock example of the data collected for individual patients as part of the review process. This had been provided previously in electronic copy only.

Complaint and ruling

Teva was very concerned about the way that such an anonymous complaint could be considered, the letter was ambiguous and contained comments that were untenable and without supporting evidence. This was not an equitable situation. It was difficult for Teva to construct an appeal as it was being asked to defend itself against events that had not occurred and against rulings for which a detailed rationale was not provided.

Teva noted that the Panel had stated in its ruling that the 'briefing material contained mixed messages' and the 'representatives' material was ambiguous'. In addition individual statements were quoted from materials (incorrectly in some instances) and single sentences were quoted in isolation from a given document and hence out of context.

Teva submitted that the Panel's ruling did not clearly define where the alleged breaches had arisen. In line with the guidance on appeals, Teva addressed the points in the order that they appeared in the ruling.

The above not withstanding, Teva addressed the following three issues in some depth as they appeared to provide the basis for the initial ruling and the alleged Clause 2 breach.

1 The Enhanced Asthma Care Service was a switch service
2 Controlled patients had not received a full clinical review
3 Provision of a 'switch letter'

1 The service was a switch service

Teva submitted that the definition of a switch service as outlined in the Code (Clause 18.4) was 'whereby a patient's medicine is simply changed to another without a clinical assessment'. The service at issue did not constitute a switch service as every asthmatic within the practice had a full clinical review consisting of 77 data sets:

Following the completion of the full clinical review the nurse presented the baseline assessment for the practice on an individual patient basis to the GP. Following review the GP made a clinical assessment and might request specific actions for individual patients which the agency nurse would implement. The service was one of the most detailed and comprehensive review services currently provided by the pharmaceutical industry. The service level was defined by the GP and might vary from practice to practice. The service was launched in March 2006 soon after the introduction of the current Code. As there were specific changes in Clause 18 relating to the provision of educational goods and services, extensive work was undertaken to ensure that the service structure fulfilled all the criteria necessary to meet the requirements of a therapeutic review as this document demonstrated.

The Panel's view of the service as a switch service was inaccurate given that each patient received a full clinical assessment before any intervention being requested/authorized by the practice.

2 Controlled patients did not receive a full clinical review (reliever use on its own did not constitute a clinical review).

Teva submitted that the major inconsistency in the ruling was that the Panel had stated that there was clinical review for uncontrolled patients and some elements of review to establish which patients were controlled. An identical data set was collected (as outlined in section 1 above) as part of a full clinical assessment for all asthma patients within participating practices ie for both controlled (defined as reliever use above an agreed level over the previous 12 months) and uncontrolled patients.

The only action that was different for controlled and uncontrolled patients was that uncontrolled patients

received a symptom questionnaire, but controlled patients did not require one, because of their low level of reliever use (defined by the practice) and no asthma symptoms in the GP notes. If the practice wished to send all asthma patients a symptom questionnaire then this could be stated on the authorization form and would be implemented by the nurse agency.

The 'electronic baseline assessment' was then presented to the practice. All 77 collected data sets relating to patients were then reviewed on an individual basis by the nurse and the GP in order for the GP to decide a course of action. Teva noted that just because a patient used a low number of reliever inhalers, that patient might have other treatment issues eg admission to hospital with an asthma attack. If so then the practice might decide that this patient was not controlled and treated the patient accordingly. The use of reliever inhalers was a marker advocated by the BTS. Therefore every patient received a full clinical review before the GP authorizing a specific course of action. Reliever use alone was not used to agree a course of action for an individual patient but rather formed part of a full clinical review.

Teva submitted that the Panel might have misunderstood that all patients whether classified as 'controlled' or 'uncontrolled' received exactly the same clinical review; it was the GP's decision as to whether specific patients or groups of patients were sent a symptom questionnaire.

Teva did not understand why the Panel did not consider that the identification on its own (reliever use) constituted a clinical review. Teva had clearly shown that all patients received a very extensive clinical review as outlined above, with SAB use being only one of 77 clinical review criteria that was collected for each patient.

Teva submitted that given that the review process was the same for controlled and uncontrolled patients it could only draw the conclusion that this met the requirements of the Code as it stated in the Panel's ruling that 'There was clinical review for the uncontrolled patients'.

3 Provision of a 'switch letter' (immediate medication change letter)

Teva stated that the Panel was incorrect to state that Teva had provided a template switch letter. Any letter (template or otherwise) that a GP wished to use was agreed and sent only after the GP had reviewed the full baseline assessment of all patients, on all 77 clinical review parameters. The letter could therefore not be deemed a 'switch' letter, which the Panel inferred as meaning that no clinical review had taken place before the letter was sent to the patient. The Panel appeared to have ruled on a document that taken out of sequence in relation to service delivery could be interpreted as a 'switch' letter.
With regard to each paragraph of the complaint, Teva noted the following:

'The complainant stated that as a current member of Teva's sales force (s)he was concerned about a part of the business which was becoming increasingly pressurised.'

Teva had an internal 'whistleblower' policy that all employees were told about on joining the company and throughout their employment. The 'alleged employee' who had complained anonymously did not follow the internal processes, and Teva was unaware that any individual felt pressurised as a direct result of being asked to recruit practices to undertake the service or they would have acted accordingly.

'The main product promoted was Qvar and representatives obviously had targets which the complainant did not have a problem with. It was how representatives were encouraged to achieve these targets that were worrying.'

Teva submitted that it had commented on this in its previous response but the allegations remained unsubstantiated.

'Representatives were asked to sign surgeries up to a non-promotional asthma review service [the Enhanced Asthma Care Service] provided by [an agency], which in turn would find patients suitable to be changed to Qvar. As this was a service that was supposed to help practices review their asthma patients and be non-promotional, it was of concern that representatives were increasingly pressurised to sign up at least six surgeries per year, which was clearly stated in the representative's mandate. It was a big issue if representatives fell behind these targets or if the form did not clearly specify a switch to Qvar or Qvar Easi-Breathe'.

Teva submitted that in terms of 'finding patients suitable for change to Qvar', this was incorrect. Practices requesting the service complete the service authorization form and specified specific patient groups that they wanted to review. Following a full clinical review these patients were then presented to the practice for the practice to decide a course of action (including no action) for each specific patient. This included a range of treatment options including non-medicinal options. The agency implemented the decision of the practice following review and acted purely as data processors under the Data Protection Act 1998. The agency could demonstrate that in many cases practices changed patients to products other than Qvar. That was their choice and would be stated on the service authorization form. It was untrue that if the authorization form did not specify a 'switch' to Qvar that this was a big issue for the representative.

The agency was an independent organisation governed by the Data Protection Act and other legislation that meant it could not pass any details contained on the authorization forms to Teva; hence Teva would be unaware if a practice completed a form in this manner. The form was not seen by any Teva management after being signed by the practice.

Each representative was required to recruit six practices in order that nursing resource could be shared in an equitable manner amongst the field force. Due to excessive demand from primary care the nursing headcount had to be increased since Teva's response to the complaint. There was a waiting list of

approximately five working weeks for practices requesting the service and being offered a date when a nurse advisor was able to commence service delivery, ie the figure of 6 practices per representative had been greatly exceeded and hence could not be viewed as a pressurised target. Demand from practices had far outstripped available nursing resource.

'If the service was purely meant to benefit the practice only, why would the company make such a big deal of setting minimum targets to be achieved by each representative? The complainant considered the unnecessary pressure coming from the top was being passed on to the customers who might be pushed unethically into something they did not want, by people whose jobs might be at risk if they did not achieve the minimum target'.

Teva noted that targets were a fact of life for many professions including representatives and doctors. Targets defined the expectation of the employer to the employee in order to create a transparent working environment. The target of six practices per representative was set to ensure that all nurse resources were fully utilised. As previously stated this target had been greatly exceeded and the representative's target had not been changed from six practices, despite the addition of a further five nurses. Given that this was the case why would it be necessary to exert unnecessary pressure from the top down if available resources were already being exceeded?

In relation to pushing practices into a service which they did not want Teva submitted the following:

- In order to request the service practices had to sign a detailed authorization form specifying their service requirements. If they did not want the service why sign up to it?
- Practices could withdraw from the service at any point either.
- Following the completion of events practices were asked to complete a questionnaire to assess the benefit of the review/clinic to patients and the benefits of the review/clinic service to the practice.

All categories were scored 0 (poor), 1 (satisfactory) or 2 (good). Teva submitted that the average score achieved across all UK practices where the service had been delivered was 2. If practices were being 'pushed unethically into something that they did not want' then the scores achieved would not represent universal satisfaction. Teva denied this allegation.

'The representative stated the (s)he had had to submit this complaint anonymously for fear of reprisal, but (s)he was sure that plenty of evidence would be found in e-mails, representative mandates etc if an investigation was launched into this matter.

Teva had re-briefed the internal whistleblower process that allowed for detailed complaints to be made anonymously. This was acted upon by senior management within the Teva organisation. As in this instant the whistleblower process was not utilised it was very difficult to investigate this anonymous complaint fully.

With regard the Panel's ruling, Teva made the following points:

'The Panel noted that the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated, inter alia, that Clauses 18.1 and 18.4 prohibited switch services paid for or facilitated directly or indirectly by a pharmaceutical company whereby a patient's medicine was simply changed to another without a clinical assessment. Companies could promote a simple switch from one product to another but not assist in the implementation of it.'

Teva submitted that the service provided a full clinical assessment for every asthmatic in a practice. This was a requirement as within the service authorization form the GP signed to authorise the following: 'We agree for READ code searches to be done to identify patients coded for Asthma. Following the patient identification we also authorise a nurse review of such patients using miquest based extraction software'. This seemed to have been missed by the Panel. The representative folder contained a 'dummy baseline' report showing the information collected as part of the clinical assessment for all asthma patients. The full clinical review comprised the collation and presentation of 77 different pieces of information, relevant to the treatment of asthma that was presented to the GP/practice for review. Additional data sets might be captured should the practice wish to send selected patients a symptom questionnaire or invite an individual for a review through a nurse run clinic. This information was collected for each patient and combined into the practice baseline assessment which was then presented to the GP for review before any course of action was decided as outlined on the flow chart.

The service did not constitute a 'switch' as defined by Clause 18.4 as every patient received a full clinical assessment before the baseline assessment was presented to the practice. When presenting the baseline assessment every patient was discussed individually with the GP and the agency then implemented the course of action requested by the practice for any particular individual.

'The Panel noted that representatives had to introduce the service during a non-promotional call using a service detail aid. The briefing material instructed the representatives to remind the Doctor of their previous conversation ie the imminent phase out of Becotide and Becloforte (CFC-containing beclometasone devices. Qvar, Teva's product was CFC-free beclomethasone). It was suggested that the phase out of Becotide and Becloforte be used as the opportunity to review all asthmatics.'

Teva submitted that the service detail aid, as stated by the Panel, was used by the representative to introduce the service to a practice during a non-promotional call. Taking practices page by page through the service detail aid was the main method of communicating how the service worked.

The detail aid stated the following on the front cover:

- Enhanced Asthma Care Service
  - Helping you to deliver improved outcomes in asthma

- Page 2 highlighted amongst others the following statements:
  - There were over 1,400 deaths from asthma in the UK in 2002
  - As many as 90% of the deaths from asthma are avoidable
  - Asthma can be very successfully treated by health professionals if time was applied and BTS/SIGN guidelines were followed

- Page 3 stated:
  - Provides a full therapeutic review of your asthma patients

- Page 7 (practice benefits) stated:
  - Clinical assessment in accordance with BTS guidelines

From the above it should be noted that the service provided the practice with a full clinical assessment of all asthma patients irrespective of whether they were on a CFC-containing inhaler or a CFC-free inhaler. Simply because a patient was on a CFC-free inhaler did not mean that their asthma was controlled.

Teva submitted that in relation to the briefing material instructing the representatives to 'remind the Doctor of their previous conversation ie the imminent phase out of Becotide and Becloforte', it assumed that the Panel was eluding to the service introduction contained within the representatives' folder (although this was not stated) and noted the following:

- There were approximately 1.8 million patients in the UK receiving prescriptions for CFC-containing beclometasone inhalers to control their asthma
- CFC-containing beclometasone inhalers would not be available for this patient group by around June 2008
- It was not an option 'to do nothing'. These patients would have to be changed to an alternative product.

Given this current environment the service introduction was introduced because many PCTs advocated a 'switch' of CFC-containing aerosol formulations to CFC-free formulations without patient review. This was not in the best interest of the patient and if simply switched to another product at an equivalent therapeutic dose uncontrolled patients would remain uncontrolled. The service introduction in the words of the Panel 'suggested that the phase out of Becotide and Becloforte be used as the opportunity to review all asthmatics'. The service introduction clearly advocated against switch. Teva failed to see how it could be more explicit in its materials, but it was currently reviewing them all in light of the Panel's comments.

It should be apparent that the service detail aid together with the service introduction advocated review in line with the BTS guidelines of all patients not just specific groups, unless directed to do so by the practice. The service introduction simply recognised that practices had to implement a CFC transition within the next year. The service as stated within the service detail aid in addition to reviewing all asthmatics could provide effective implementation of a CFC transition programme. The main message was to review patients before considering a change. This was a very responsible message to give to practices and was in line with the General Practitioner in Airways Group's advice given on their web-site. The transition was going to happen anyway, Teva wanted to use it as an opportunity to improve asthma care.

'The representative was instructed to tell the doctor that the service could help him: provide a full therapeutic review of all asthmatics; identify controlled asthmatics for a straight change to a CFC-free equivalent for both metered dose inhalers and breath actuated inhalers if required and identify sub-optimally controlled patients for review through a clinic.'

Teva noted the above statement whilst factually correct must be taken in context within which it was presented to practices as well as the current environment. The Panel had again eluded to the service introduction contained within section 7 of the representative training folders provided. It had already been highlighted that the service detail aid contained the main communication messages in relation to the promotion of the service.

The service introduction could be used with practices interested in implementing a CFC transition as part of the service. There were approximately 1.8 million UK patients on CFC-containing beclometasone aerosols who would have to be changed to another product within the next year. The NHS did not have the resources to provide an extra 1.8 million face to face consultations. Therefore the basis of Teva's communication was that some practices would like to identify controlled patients, defined as controlled following GP review of the 77 data fields per patient contained within the clinical assessment and submitted as part of the practice baseline assessment 'for a straight change to a CFC-free equivalent for both metered dose inhalers and breath actuated inhalers if required' and deployed the nurse advisors to review within a face to face consultation the uncontrolled patients which the practice selected following the same review. Teva stressed however that if the practice wished every patient within the practice to have a face to face consultation then it would implement that action. As stated above the service provided a full therapeutic review for all asthmatics. It appeared that the Panel had quoted one or two sentences in isolation from the whole document highlighting them out of the original context. The service introduction discouraged against 'switch', did not advocate switch, as the Panel implied. The item advocated 'reviewing asthma patients prior to the transition'.

The briefing material did not mention the BTS/SIGN guidelines.

Teva noted that the Panel incorrectly stated that the briefing material did not mention the BTS/SIGN guidelines. The BTS guidelines were mentioned in the following service materials utilised by the sales force with practices:

- The service bridging piece – brief description of the service left with the GP during a promotional call
- The service detail aid (this was presented to all practices during the non promotional call) – the BTS guidelines were mentioned on pages 2, 5 and 7
- The service introduction did not re-state the BTS/SIGN guidelines as these messages would have been made clear to the practice when the representative presented the service detail aid. There was no need for repetition. The service introduction would be used to support page 7 of the detail aid (practice benefits) when presenting the bullet point 'Can provide effective implementation of a CFC-Free transition programme.'

In addition other service materials eg the representatives' briefing document clearly stated that 'The objective of the Enhanced Asthma Care Service is to provide General Practice with a facilitation platform for the systematic identification and review of asthmatic patients in line with the BTS/SIGN guidelines'.

'Representatives were briefed to state that the result of the service was that 'CFC transition is implemented for the practice and patient care is optimised for your asthmatic patients'. The service detail aid itself stated that one of the benefits of the service was that it could provide an effective implementation of a CFC-free transition programme. This benefit was, however, listed after other benefits which referred to clinical assessment and the BTS guidelines.'

Teva submitted that as contained within the service detail aid, the service could provide an effective implementation of a CFC-free transition programme following a full clinical assessment, however 'The objective of the Enhanced Asthma Care Service is to provide General Practice with a facilitation platform for the systematic identification and review of asthmatic patients in line with the BTS/SIGN guidelines'. Teva submitted that it could not have made this any clearer in its customer facing documents or indeed representative briefing material.

'The Panel noted that with regard to patient identification, poorly controlled asthmatics were defined as those who used an agreed number of short acting bronchodilators over a 12 month period. These people would be sent a symptom questionnaire. The Panel assumed that if patients had used less than the agreed number of short acting bronchodilators over a 12 month period then they would be defined as controlled asthmatics. In this regard, however, the Panel considered that merely noting a patient's use of reliever medication was only a surrogate marker for asthma control. It was possible that some patients who did not use a lot of short acting bronchodilators were nonetheless not optimally controlled. The Panel did not consider such identification on its own constituted clinical review.'
Teva submitted that this appeared to be one of the major misunderstandings in the Panel's ruling and why it considered that the service was a 'switch service'.

An identical data set was collected as part of a full clinical assessment for all asthma patients within participating practices ie for both controlled (defined as reliever use above an agreed level over the previous 12 months) and uncontrolled patients. This comprised an additional 76 data sets (in addition to reliever use) that were collected for all patients as part of the clinical assessment and constituted the 'electronic baseline assessment'.

- Therefore the only action that was different for controlled and uncontrolled patients was that uncontrolled patients received a symptom questionnaire but controlled patients did not require one because of their low level of reliever use (defined by the practice) and no asthma symptoms in the GP notes. Teva noted that if the practice wished to send all asthma patients a symptom questionnaire then this could be stated on the authorization form and would be implemented by the agency if required.

- The 'electronic baseline assessment' was then presented to the practice. All 77 collected data sets relating to patients were then reviewed on an individual basis by the nurse and the GP in order for the GP to decide a course of action. This could clearly be seen on of the service authorization form. It should be noted that even if a patient used a low number of reliever inhalers, that patient might have other treatment issues eg admission to hospital with an asthma attack, then the practice might decide that the patient was not controlled and treat the patient accordingly. Reliever use was only used as an initial marker for asthma control. The use of reliever inhalers was a marker advocated by the BTS. In other words every patient received a full clinical review prior to the GP authorizing a specific course of action and SABA use alone was not used to agree a course of action for an individual patient.

Controlled patients were therefore treated in exactly the same way as uncontrolled patients, the same data sets were collected for both groups of patients and no action was taken for any patient without a full clinical assessment and presentation of the baseline assessment to the GP. The GP would authorize mandated actions at this point.

BTS/SIGN recognised and stated that the level of use of short-acting bronchodilators 'is a marker of poorly controlled asthma'. The use of short-acting bronchodilators (relievers) was a well recognised marker within primary care in assessing asthma control and was referenced as such on all national and international guidelines published on asthma. Teva included a synopsis of the guidelines and the affirmation of the importance of reliever usage as a marker of asthma control.

Teva submitted that putting aside the statement in the Panel's ruling that 'a patient's use of reliever medication was only a surrogate marker for asthma control' national and international guidelines suggested the contrary. Teva had evidence that other industry services used reliever use alone to define an uncontrolled patient. In relation to the comment that

reliever use alone did not constitute a clinical review Teva agreed and this was why a much broader clinical review was conducted as part of the service.

'The Panel noted that it was stated that the nurse advisors would identify all patients that satisfied the review inclusion criteria that the representatives has discussed and agreed with the lead GP in the practice. The instructions to representatives stated that the service design could focus on either patient control and symptoms or CFC transition. The advantages included 'enables practice to complete CFC transition.'

Teva submitted that the service authorization form allowed the practice to confirm exactly which patients that it wished to review. The GP performed the role of Data Controller as defined within the Data Protection Act 1998. Whether a CFC-free transition was incorporated as part of the service depended on practice choice.

'The representative's responsibilities with regard to completion of the practice mandate included confirmation of 'which ICS (inhaled corticosteroids) patients were to be reviewed – patients receiving CFC-containing or all patients.'

Teva submitted that the representative fulfilled an administrative role in relation to the service and simply asked the practice to confirm on the service authorization form which patient groups the practice would like to review. The choice of patients reviewed was the decision of the practice as it controlled the service at all times. The agency simply implemented the practice requirements.

'The Panel considered there was a discrepancy within the instructions and with regard to the selection criteria for practices to be offered the service, and queried whether the primary selection criterion really was that they must have key GPs and staff who realised the importance of identifying and reviewing asthma patients who were sub-optimally controlled and should be established on a more effective therapy.'

Teva noted that the clinical assessment completed for all asthma patients within the practice could only serve to help identify patients who needed additional review. Given that there were still 1,400 deaths due to asthma per year according to Asthma UK, which also stated that as many as 90% of the deaths were preventable - the service could help to address this situation. The Panel's statement outlined above was not helpful as it stated that it queried the primary selection criteria but did not state its findings. Teva noted that practices undertaking the service signed to state 'that the services provided are in the best medical interest of our patients and that we (GPs), retain complete control of the service at all times'. The service was in the interest of patients and benefited the NHS whilst maintaining patient care.

'The representatives training presentation detailed the representatives on-going role once the practice had signed up to the programme and they were told that this was the start not the end of their role. When scheduling the first date for [agency] staff to attend the surgery representatives were to make sure that they could be there to inter alia, remind the practice of the sponsor and 'Build the relationship three ways'. The representative was to keep in regular contact with the practice.'

Teva submitted that the representative's role was purely administrative in relation to the delivery of the service. The representative took agency staff into the practice, introduced them, and then left to carry out their normal day's activities. It was only courteous for the sponsor to introduce the agency personnel to the practice. The service was expensive and Teva was trying to build its pedigree as a market-leading respiratory house. The service would assist the practice in the pro-active management of its asthma patients. As the local nurse advisor was likely to deliver the service to other practices within that representative's geography the phrase 'building the relationship three ways' was meant to convey a spirit of partnership between the supplier and sponsor ie agency and the representative. The training slides were presented at a national conference. The representative might for example provide practical administrative advice to the nurse on 'how to find the practice, the best place to park' etc. These messages were contained within the verbal commentary covering the presentation of the slides. The representative was briefed to keep in regular contact with the practice following the service provision as permitted by the Code. When companies delivered an added-value service to a customer they wanted to ensure that the service and its implementation met with practice approval.

'No advice was given in the presentation regarding the relevant clauses of the Code and the limited non-promotional role of the representative once the practice had signed up.'

Teva submitted that representatives received ABPI training on their initial training course (details were given). Additionally all representatives were asked to read through Clause 18 of the Code and they sat the ABPI examination.

Teva submitted that it was incorrect to state that no advice was given regarding the relevant clauses of the Code. Immediately before the service presentation the sales force received a presentation in relation to the Code, including the provision of added-value services. Information on ABPI training was not initially requested by the Panel. All representatives as part of their initial training received this presentation.

It should also be noted that the service representative training document stated the requirements of the Code in relation to the provision of medical and educational goods and services.

Teva submitted that also as part of the training all representatives were required to sit the ABPI examination. This ensured that they were fully conversant with the Code and its application to medical and educational goods and services at the time of the training. The examinations were marked and the representatives de-briefed. Anyone who failed the

examination was asked to successfully complete the examination prior to discussing the service with practices.

'The Panel noted Teva's comments about some PCT's approach in switching patients form CFC to CFC-free treatment without patient review. It appeared from the materials submitted that it was possible for a practice to decide to use the Teva service for such a switch.'

Teva submitted that this was not possible. Practices signing up to the service, on the authorization form, agreed that following the patient identification a nurse review was conducted. As the miquest based extraction tool identified and conducted a clinical assessment at the same time, it was not possible to identify patients without conducting a full clinical assessment. A 'switch' was therefore technically not possible.

'Documentation in this regard was included in the Teva service e.g. the practice treatment mandate. The practice treatment mandate identified five groups of patients: Group 1 was controlled on CFC corticosteroids; Group 2 was controlled on CFC-free corticosteroids; Groups 3 and 4 were sub-optimally controlled either on CFC or CFC free corticosteroids and Group 5 were non-responders.'

Teva submitted that the service identified and produced a full clinical assessment for all patients at steps 1 to 5 of the BTS/SIGN guidelines. In addition to the treatment mandate described above the practice also confirmed a treatment protocol for all other patient groups within the service authorization form.

'A template letter, headed 'EACS Immediate Medication Change', was also provided which appeared to indicate that the patient was being switched from CFC to CFC-free without clinical review.'

Teva submitted that this was factually incorrect. Any course of action for any patient was only authorized by the GP following a full clinical assessment and the GP having reviewed the practice baseline assessment and discussed each individual patient. All letters relating to service delivery were only used after this point. There was a whole range of template service letters to cover all likely service outcomes. The practice might use the template letters provided, modify their content or indeed use their own letter providing it met with Code requirements. All template letters utilised on the service had been provided previously.

'The Panel queried why such a template letter should be provided at all if practices were chosen because they wanted to identify and review asthma patients who were sub-optimally controlled and establish them on a more effective therapy.'

Teva submitted that the immediate medication change letter was used when the practice had decided that following a full clinical assessment it wished to change patients to a different medicine without a face to face consultation. In such instances most practices informed the patient of the change by letter. The provision of template letters was purely to save the practice time in creating its own. Most practices responded positively to the provision of such a letter. There was a range of template letters used on the service.

'A number of items in the training materials referred to the service enabling practice to complete CFC transition. The Panel noted its comments above about the discrepancy between the stated aims of the service and the training and other materials.'

Teva disagreed with the Panel's comments. It had to accept that the CFC transition was high on the agenda of most practices and PCTs at present. The materials clearly communicated the practice benefits that could be achieved as a direct result of the service; these included but were not limited to a CFC transition. Indeed the service detail aid listed the practice benefits as follows:

- Proactively identify patient's current level of asthma control at each step of the BTS guidelines
- Full therapeutic review of those patients needing further review or medication change to improve their control
- Patients attending clinic would have their inhaler technique assessed to ensure that they could use their device properly
- Clinical assessment, in accordance with the BTS guidelines, including key measures to help meet GMS targets and achieve QOF points through the completion of asthma templates
- Could provide effective implementation of a CFC-free transition programme
- Identify controlled patients for potential step down in line with BTS/SIGN guidelines
- Identify patients whose treatment regime falls outside of current guidelines for review e.g. high dose steroid/long-acting beta agonist without inhaled corticosteroids
- Extra resources to assist the practice improve outcomes in asthma.

Teva submitted that the service benefits highlighted above were a fair representation of the benefits delivered to practices which might request the service.

'There were no instructions about what representatives and nurse advisors were to do if all the practice required was a switch form CFC to CFC-free treatment. This was a significant omission.'

Teva submitted that as previously stated, representatives and nurse advisors had been trained and informed that a 'switch' was not permissible under the Code. This was the message that representatives had been briefed to give to practices. If this was a 'significant omission' Teva considered it should have been clarified with Teva prior to the Panel making its ruling.

In addition Teva's service material, namely the representatives' briefing document informed the representative that 'Clause 18.4 prohibits switch services'. Hence the representative was clearly briefed not to promote the service as a 'switch' service.

'The Panel had some serious concerns about the

arrangements for the service in question and noted that switch services were expressly prohibited under the Code. In this regard the Panel specifically queried the representatives' role in discussing and agreeing inclusion criteria with the GP, the possible inclusion of patients controlled on CFC corticosteroid preparations and the provision of a template 'switch' letter.'

Teva submitted that the representative confirmed which patients the practice wished to review ie had a purely administrative role in assisting the practice to complete certain sections of the service authorization form and this activity was permissible under the Code. Teva did not provide a template 'switch' letter as previously discussed. The Panel's ruling contained many repetitions of the same point which Teva had addressed earlier.

In relation to the inclusion of patients controlled on a CFC corticosteroid the BTS advocated the review of all patients every three months in order to ensure that the patient's asthma was controlled on the lowest effective dose of their medicine. Not only was this a legitimate group of patients to review, their review could potentially result in significant savings being achieved by the NHS in relation to prescription costs.

'In the Panel's view the representatives' briefing material contained mixed messages regarding switch programmes. On one hand representatives were reminded that switch services were prohibited, on the other they were told to 'sell' the service on the basis that, inter alia, prescribers could use it to identify controlled patients and do a straight change to a CFC beclomethasone product (CFC transition appeared to be a greater priority than clinical assessment of patients); template letters for immediate medication change were provided.'

Teva submitted that representatives' training materials made it abundantly clear that 'switch' services were prohibited. Teva was reviewing all training materials in line with the ruling.

Teva noted that the Panel had changed the words from how they appeared within the service introduction. It stated 'Identify controlled patients and do a straight change to a CFC beclomethasone product'. However, the service introduction stated 'identify controlled patients (defined by you) for a straight change to a CFC free equivalent for both MDI and BAI inhalers if required'.

At no point did the service material state a CFC-free beclometasone product. This was an incorrect and invalid insertion. Teva was disappointed that these inaccuracies were not picked up by the Panel and rectified before release of the ruling. This was a fundamental flaw in the Panel's ruling as this wording could constitute grounds for a reader to believe the service was designed for 'switch' purposes. A CFC-free equivalent could mean a number of ICS molecules eg fluticasone, budesonide, mometasone, ciclesonide or indeed the change to a combination inhaler.

'The Panel considered that the material for the service should have been consistent and made it abundantly clear that switch services without clinical assessment were wholly unacceptable. There should have been no room for doubt.'

Teva submitted that the service materials conveyed the required messages in line with the Code.

'On balance the Panel considered that the representatives' briefing material was ambiguous such that it might be seen by some as advocating a course of action which was likely to lead to a breach of the Code as alleged.'

If this point was in relation to a breach of Clause 15.9 Teva was willing to accept this ruling. Teva had however endeavoured to communicate a sophisticated asthma review service in as consistent a manner as possible.

'The Panel then considered whether the circumstances were such that a formal report under paragraph 8.2 of the Constitution and Procedure should be made to the Code of Practice Appeal Board. The Panel decided not to make such a report as there was clinical review for uncontrolled patients and some element of review to establish which patients were controlled. Some of the instructions referred to the requirements of Clauses 18.1 and 18.4 and their supplementary information.'

Teva submitted that controlled patients and uncontrolled patients received the same review process ie a full clinical assessment and such an assessment was then presented to the GP in the form of a baseline assessment in order that the GP could decide an appropriate course of action for each patient. The Panel presumed (incorrectly) that reliever use only formed the clinical review for controlled patients. This was incorrect. Given that assumption Teva could see why the Panel might have ruled the service in breach of Clauses 18.1 and 18.4 as it would become a 'switch' service. This was a significant issue that needed to be addressed by the Appeal Board.

In conclusion Teva noted that the Panel as outlined above had made three major and incorrect assumptions in reaching its ruling:

- The service was a switch service
- Controlled patients did not receive a full clinical review
- A 'switch letter' was provided as part of the service.

Teva submitted that its appeal unambiguously proved, together with the service documents provided, that that these assumptions were not valid. Teva's comments together with its initial submission demonstrated that the service and materials complied fully with Clauses 18.1, 18.4 and 9.1 of the Code. Teva submitted that it was not in breach of Clause 2.

APPEAL BOARD RULING

The Appeal Board acknowledged the clinical value of a review service in asthma given the number of uncontrolled patients and the imminent discontinuation of CFC corticosteroid inhalers. Very many patients even if well controlled, would soon have

to be changed over from CFC-containing products to CFC-free alternatives.

The Appeal Board noted that practices were offered the service in question before representatives knew what their prescribing choices would be. In that regard the asthma review service was not linked to the prescription of any medicine. No breach of Clause 18.1 was ruled. The appeal on this point was successful.

The Appeal Board, however, noted that section 2B of the Practice Treatment Mandate had to be completed by the Teva representative and the GP. In such circumstances the Appeal Board considered it highly likely that, where such therapy was appropriate, the GP would feel pressurised to specify Qvar, Teva's CFC-free beclometasone. The Appeal Board considered it unacceptable for the representative to be present when the GP recorded his/her prescribing decision and in this regard upheld the Panel's ruling of a breach of Clause 18.4 of the Code. The appeal on this point was unsuccessful.

Notwithstanding its ruling of a breach of Clause 18.4 of the Code, overall the Appeal Board did not consider that high standards had not been maintained. No breach of Clause 9.1 was ruled. It thus followed that there was no breach of Clause 2 of the Code and the Appeal Board ruled accordingly. The appeal on these points was successful.

Complaint received	**3 July 2007**
Case completed	**10 December 2007**