CASE AUTH/2352/8/10

GLAXOSMITHKLINE v CHIESI

Clinical Support Service

GlaxoSmithKline alleged that Chiesi had facilitated a switch service rather than a genuine therapeutic review. This was specifically prohibited under the Code. GlaxoSmithKline considered that the service did not offer a comprehensive range of relevant treatment choices, but was limited by the prescribing instructions given to practices by the local primary care pharmacy services and that Chiesi was aware of these instructions but continued to support the implementation. GlaxoSmithKline also considered that the clinical assessments carried out by the pharmacists employed by Chiesi were inadequate to ensure that patient care was enhanced or maintained.

GlaxoSmithKline obtained evidence of this activity from a letter sent by a GP to a patient which stated:

> **'We are currently carrying out a review of our patients on Seretide 125 Evohalers. I would like to advise you that our practice policy has recently been changed and that from now on we will be prescribing Fostair 100/6 inhalers instead.'**

The letter reassured the patient regarding the change and offered an appointment if needed, thus it was apparent that no discussion with the patient had taken place as part of a clinical review, and the change was initiated without informed consent. The footer on the letter made it clear that this review had taken place under the auspices of 'A therapeutic review service provided as a service to medicine by Chiesi Limited'.

GlaxoSmithKline submitted that the letter clearly suggested that patients were switched from Seretide 125 Evohaler to Fostair 100/6 inhaler due to a change in 'practice policy', rather than a clinical assessment of individual patient's needs. As such GlaxoSmithKline believed that Chiesi had supported a switch service rather than a genuine therapeutic review of asthma patients. Further, GlaxoSmithKline submitted that in inter-company correspondence the review implemented by Chiesi appeared to be a notes review which, for the treatment of asthma, did not represent good clinical practice (Thomas *et al* 2009, Doyle *et al* 2010).

GlaxoSmithKline also provided a copy of an email from the local health board to practice managers which encouraged GP practices to take up Chiesi's offer of a 'therapeutic review' service and detailed three areas of prescribing covered by Chiesi's service. A comprehensive range of therapeutic options was not listed as required by the Code to ensure a genuine therapeutic review. Chiesi informed GlaxoSmithKline that it had received a copy of this email from the primary care trust (PCT) and so knew of the very limited therapeutic options being recommended yet continued to facilitate this service. The email listed the product/s that patients could be transferred to.

GlaxoSmithKline alleged that as the choice of medicines to be used following the reviews was very limited, the services could not be true therapeutic reviews.

Furthermore, GlaxoSmithKline considered that a *bona fide* therapeutic review should be closely aligned to best practice guidelines in a particular therapy area. Therefore a therapeutic asthma review should closely follow the British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) asthma guidelines, which were generally considered to represent best practice in asthma management. Patients who currently received Seretide 125 were already at step 3 (of 5) of these guidelines and had moderately severe disease which required careful clinical assessment to ensure optimal treatment of what was a potentially life-threatening condition. The guidelines stipulated that 'All people with asthma should have access to primary care services delivered by doctors and nurses with appropriate training in asthma management' and that in a structured review 'All patients should be reviewed regularly by a doctor or nurse with appropriate training in asthma management. The review should incorporate a written action plan'. The use of pharmacists to conduct the 'clinical assessment' of these patients was at odds with this recommendation as was the lack of any written action plan.

The guidelines also focussed on identifying patients whose asthma was under- or over-treated and increasing or decreasing their treatments in line with a well-defined treatment ladder. The Chiesi service, as described in the email, focussed solely on switching patients between different medicines on the same rung of the treatment ladder. Such switches were not recommended within the BTS/SIGN guidelines.

GlaxoSmithKline considered that Chiesi's admitted knowledge of the content of the email to practices from the local NHS meant it knew about the limited therapeutic options being recommended for its Clinical Support Service (CSS) but continued to support and facilitate the prescription changes which thus made it responsible under the Code. The clinical assessments carried out for moderately severe asthma patients were inadequate. Given these concerns, GlaxoSmithKline believed that Chiesi's CSS was a switch programme that failed to

maintain high standards and might impact on patient safety and the reputation of the pharmaceutical industry contrary to Clause 2.

The detailed response from Chiesi is given below.

The Panel noted Chiesi's submission that the CSS had assisted the local health board, under an arrangement akin to a joint working partnership, for a number of years. Chiesi had referred to the ABPI guidance notes on joint working between pharmaceutical companies and the NHS. In the Panel's view the CSS was service provision, not joint working. Joint working covered situations where, for the benefit of patients, the NHS and one or more pharmaceutical companies pooled skills, experience and/or resources with a shared commitment to successful delivery of patient centered projects. Each party had to make a significant contribution and outcomes had to be measured. Treatments must be in line with nationally accepted clinical guidance where such existed and the arrangements between the parties must be open and transparent.

The Panel noted that GlaxoSmithKline had alleged that the current service, a review based on patients' medical records, was insufficient to enhance patient care or benefit the NHS and maintain patient care.

The Clinical Support Service Protocol explained that the service would enable primary care organisations and individual practices to carry out clinical assessments and therapeutic reviews of specific patient groups. The service was non promotional and non product specific. The GP retained full control of the process at all times.

The SOP Procedure for Asthma Therapeutic Review began by referring to asthma control and the BTS/SIGN guidelines 2008. The introduction stated that when deemed necessary, an asthma clinic could be used to optimise patients' asthma control and provide reinforcement and education on the importance and achievability of good asthma control and hence improve quality of life. The CSS pharmacist would clarify with the GP whether the review was conducted with or without the patient. Factors which determined this included whether after clinical assessment any potential changes to a patient's asthma treatment might result in a change of molecule or device but would ultimately be determined by the GP's instructions. If the GP chose a paper review the Asthma Therapeutic Review Authorization Form (Non-Clinic) would be completed and identify: which patient groups should be reviewed; what the GP's treatments of choice were; which strengths should be used and any special instructions. The form stated that patients would be reviewed in accordance with BTS and National Institute for health and Clinical Excellence (NICE) Guidelines. Products were listed beneath the following headings: short-acting beta$_2$ agonists, long acting beta$_2$ agonists, inhaled corticosteroids, fixed inhaled corticosteroids/long-acting beta-agonist (ICS/LABA) combinations and others.

The Therapeutic Review Project Specification Form set out the services to be provided to the GP practice and the terms of service of a patient record review. It was noted that the result of a clinical assessment might require a face-to-face clinical assessment, possible changes in treatment including changes of dose, medicine or cessation of treatment. No medicines would be changed unless authorized by the GP or if, in the clinical judgement of the pharmacist, there was a query which required resolution or discussion by or with the GP. The GP and pharmacist would meet at the end of each working day and at the end of the review so, *inter alia*, the GP could summarize the completed work and authorize any further actions required. The authorizing GP was asked to sign each page of the patient lists to indicate that they were 'fully happy' with the action taken.

The Panel noted that GlaxoSmithKline had provided a patient letter dated 5 October 2009 to support its allegations about the current service. The Panel noted that the standard operating procedure (SOP) contemporaneous to the patient letter appeared to describe a different service, it was dated 2 April 2009. It described a review based on clinical assessment of a patient's records alone. There was no reference to a patient clinic. The GP authorized each step. The Panel did not have all the documentation for this review but considered that GlaxoSmithKline had not made specific allegations about it. In the Panel's view, the only issue to consider was whether a medical record review was adequate to, *inter alia*, enhance or maintain patient care.

The Panel noted that Thomas *et al* was a 2 year retrospective matched cohort study which evaluated the impact on asthma control of inhaler device switching without an accompanying consultation in general practice and determined that such a switch was associated with worsening asthma control. Doyle *et al* undertook qualitative interviews with 19 asthma patients who had experienced a non-consented switch of their inhaler device and concluded that such switches may, *inter alia*, diminish self-control associated with good asthma management. The Panel noted that there was some evidence in relation to changing a patient's device without consent. No clinical evidence had been submitted in relation to other changes such as a change in molecule, dose, etc. The Panel noted, however, that the CSS, based on patients' records, could potentially involve a change of device.

The Panel noted GlaxoSmithKline further considered that a *bona fide* therapeutic review should be closely aligned to BTS/SIGN best practice guidelines. As an example GlaxoSmithKline noted that moderately severe asthmatics on Seretide 125 were already at step 3 (of 5) of the BTS guidelines and required careful clinical assessment. The guidelines referred to access to primary care services delivered by doctors and nurses with appropriate training in asthma management and GlaxoSmithKline alleged

that the use of pharmacists was at odds with this recommendation as was any written action plan. The Panel noted the BTS/SIGN guidelines and reference to clinical review by a nurse or doctor. The Panel noted that the guidelines were referred to in the introduction to the current SOP. The Panel did not consider that a medical record review by a pharmacist as part of the CSS meant that ongoing clinical care from a nurse or doctor was in any way precluded as implied by GlaxoSmithKline.

The Panel noted the SOP training document for pharmacists. The decision to have a medical notes review or clinic was taken by the authorizing GP. The SOP Procedure for Asthma Therapeutic Review and the SOP Training Document for Pharmacists made it clear that in some circumstances a clinic review might be preferable.

The authorizing GP defined the scope of the review, identified appropriate patients and had the final word on all matters in relation to it including product changes. In such circumstances the Panel did not consider that on the information before it about the current service a review of patients' records by a pharmacist in principle failed to enhance patient care or benefit the NHS and maintain patient care as alleged. No breach of the Code was ruled. The Panel consequently ruled no breach of Clause 2.

The Panel noted that the email from the local NHS primary care pharmacy services encouraged practices to take up the assistance of the CSS to complete the three tasks outlined in the email. The first task was to review patients using CFC containing beclometasone inhalers and transfer them to CFC-free inhalers. The local formulary options were listed – Clenil modulite or Qvar for adults over 12 and Clenil Modulite for children. The second review was of Seretide 125 MDI patients with a possibility of transfer to Fostair MDI which was described as a local formulary option and a cost effective alternative to Seretide 125 MDI. The final option described assistance to optimize the prescribing of tramadol to the formulary preferred option of Maxitram SR.

The Panel accepted, in general, that when *bona fide* therapeutic reviews were offered to practices the prescriber would, nonetheless, be aware which products were on the local formulary and he/she might decide, as a result of the review, that such products were suitable therapeutic options. However, in the view of the Panel, the content of the service and way it was offered must comply with the Code. Irrespective of what products were on the local formulary the review must offer the prescriber a comprehensive range of treatment choices. Pharmaceutical company assistance in the implementation of a switch service was unacceptable.

In the view of the Panel the email to practices from the local primary care pharmacy services was such that the prescriber's choice was, in effect, restricted to switching to those products mentioned therein. Practices would attach the greatest weight to the email. It was entirely unclear from Chiesi's responses what it knew about how the service would be introduced to local practices at the outset by the local health board other than such instruction would be by email. The Panel considered that on receipt of a copy of the email Chiesi knew that the local primary care pharmacy services was encouraging GPs to use its service in a way that rendered its provision in breach of the Code. That the email was sent independently and that Chiesi submitted that it had no prior knowledge of its content before it received a confidential copy was irrelevant. Once Chiesi knew about the email then it also knew that GPs were being encouraged to use the CS service to effect a switch programme. This was compounded by the wholly unacceptable provision by Chiesi of the email and the company's response to the local CSS pharmacist. The Panel had not seen the covering email provided to the local CSS pharmacist. Nonetheless it appeared that the local CSS pharmacist might have in effect been instructed to implement a switch service. Overall, the Panel considered that the arrangements did not meet the requirements of the Code and a breach was ruled, which was upheld on appeal by Chiesi. High standards had not been maintained. A breach of the Code was ruled which was upheld on appeal by Chiesi. The Panel considered that the provision of a switch service brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled which was upheld on appeal by Chiesi.

GlaxoSmithKline UK Ltd complained about a Clinical Support Service (CSS) run by Chiesi Limited in one particular NHS area. Inter-company dialogue had failed to resolve the matter.

COMPLAINT

GlaxoSmithKline alleged that Chiesi had facilitated a switch service rather than a genuine therapeutic review in the local NHS area. This was specifically prohibited under the Code. GlaxoSmithKline considered that the service did not offer a comprehensive range of relevant treatment choices, but was limited by the prescribing instructions given to practices by the local primary care pharmacy services and that Chiesi was aware of these instructions but continued to support the implementation. GlaxoSmithKline also considered that the clinical assessments carried out by the pharmacists employed by Chiesi were inadequate to ensure that patient care was enhanced or maintained.

GlaxoSmithKline obtained evidence of this activity from a letter sent by a GP to a patient which informed them of a switch of their inhaler as part of 'A therapeutic review service provided as a service to medicine by Chiesi Limited' and from an email from the local health board which encouraged GPs to take up Chiesi's offer of a 'therapeutic review' service and detailed the areas of prescribing covered by Chiesi's service. A comprehensive range

of therapeutic options was not listed as required by the Code to ensure a genuine therapeutic review. Chiesi informed GlaxoSmithKline that it had received a copy of this email from the primary care trust (PCT) and so it knew about the very limited therapeutic options being recommended yet continued to facilitate this service.

GlaxoSmithKline understood that similar activity was taking place in other parts of the country.

Letter

This letter, dated 5 October 2009, sent by a GP practice to a patient, stated:

'We are currently carrying out a review of our patients on Seretide 125 Evohalers. I would like to advise you that our practice policy has recently been changed and that from now on we will be prescribing Fostair 100/6 inhalers instead.'

The letter reassured the patient regarding the change and offered an appointment if needed, thus it was apparent that no discussion with the patient had taken place as part of a clinical review, and the change was initiated without informed consent. The footer on the letter made it clear that this review had taken place under the auspices of 'A therapeutic review service provided as a service to medicine by Chiesi Limited'.

In inter-company correspondence Chiesi stated that 'The pharmacist will assess individual patient records and carry out a full clinical assessment of each patient's medicine(s) and medicine history prior to any therapy review taking place'. Chiesi stated that when its pharmacists provided the CSS they:

- Assessed each patient's medicine(s) to ensure any therapy review requested and authorised by the GP was appropriate
- Checked for medicine interactions
- Checked for over or under ordering of medicines
- Checked for duplicate therapies
- Assessed compliance issues
- Assessed dosages and strengths to ensure they were correct
- Checked licensed indications
- Reviewed quantities issued and identified in-equivalence of quantities
- Checked all clinical investigations were up-to-date and identified any tests which were overdue or not recorded
- Assessed potential side effects
- Assessed possible strength optimisation.

None of the above referred to any discussion with the patient about their condition, but were, in effect, a notes review. For the treatment of asthma, a potentially life-threatening condition, this was inadequate and did not represent good clinical practice. A 2 year, retrospective, cohort study by Thomas *et al* (2009) showed that patients whose asthma medicine was switched without their consent experienced worse asthma control; patients were significantly more likely to experience unsuccessful treatment and significantly less likely to experience successful treatment than patients who were not switched without consent. The authors concluded that switching without face-to-face discussion was inadvisable. Doyle *et al* (2010) also highlighted the need for clear and open communication with patients, as switching inhalers without consent could reduce their confidence in asthma medicine and perception of control over their disease. The Code required that therapy reviews must enhance or at least maintain patient care, but the lack of one-to-one clinical discussion with the patient about their asthma treatment before treatment change meant that this tenet was not observed.

The letter clearly suggested that patients were switched from Seretide 125 Evohaler to Fostair 100/6 inhaler due to a change in 'practice policy', rather than a clinical assessment of individual patient's needs. As such GlaxoSmithKline believed that Chiesi had supported a switch service rather than a genuine therapeutic review of asthma patients.

Email

GlaxoSmithKline submitted that the document provided was part of an email sent to practice managers by the local health board. It stated that Chiesi would support therapeutic review services in three specific areas and urged practices to take up Chiesi's offer to review the following:

1 Asthma patients who used CFC-containing beclomethasone inhalers with a view to switching them to CFC-free devices the choice of which was limited to either Clenil Modulite (a Chiesi product) or Qvar for adults and solely to Clenil Modulite for patients below the age of 12.

2 Patients who used Seretide 125 Evohaler 'with possibility to transfer to Fostair MDI' (a Chiesi product).

3 Patients on various modified-release formulations of tramadol, with a view to switching them to Maxitram SR, (a Chiesi product), the local formulary preferred option.

GlaxoSmithKline alleged that as the choice of medicines to be used following the above reviews was very limited, the services could not be true therapeutic reviews. Clearly a PCT or health board might ask practices to engage in wholesale switching, and companies might promote simple switching from one product to another, but it was unacceptable for a pharmaceutical company to facilitate that switching even by means of a third party such as a sponsored nurse.

The Chiesi CSS had been the subject of two previous cases; in Case AUTH/2097/2/08 a competitor complained and in Case AUTH/2103/3/08

an anonymous PCT member complained. In both cases the Panel found no breach of the Code. In the first case the competitor company submitted two pharmacist forms from the CSS pharmacist indicating there was likely to be an increased use of Clenil Modulite (the Chiesi CFC-free pMDI) and a corresponding decrease in use of CFC-containing beclomethasone pMDIs. The Panel considered on the basis of the limited evidence before it that there was no evidence to show that the service as a whole was limited to Trinity-Chiesi products or that any inducement had been offered or given.

In the second case, the complainant provided no documentary evidence but considered that changing from CFC-containing beclomethasone pMDIs to the Chiesi CFC-free beclomethasone pMDI was done without therapeutic review. CFC-containing pMDIs were being phased out so patients on those medicines would have to be transferred to others. Chiesi provided details of its CSS. The Panel was concerned that some examples of the patient letters appeared to indicate that as a result of the CSS patients would be changed to Trinity-Chiesi's product, but the complainant provided no evidence that the CSS was a switch service. The Panel ruled no breach.

GlaxoSmithKline submitted that its complaint was different as it provided evidence that Chiesi knew of the limited therapeutic options available to local GPs and the inadequacy of the review service for moderately severe asthma patients.

The Code made clear that for a therapeutic review service sponsored by a pharmaceutical company to be acceptable, a comprehensive range of treatments (including non-medicinal ones) must be available to the prescriber, not simply those of the sponsoring company. In inter-company correspondence, Chiesi asserted that each GP determined the 'medications to be considered based on the comprehensive range of medications which is available to him/her generally or from their own formulae'. However, the email to practice managers clearly stated which 'areas of prescribing can be covered by this external support service' and then gave very limited options for each of the three areas. Chiesi stated that it was sent a copy of this email 'in confidence directly from the local health board' and it had no input or prior knowledge of its content until its receipt. However, on its receipt, Chiesi then knew of the very limited options being made available to prescribers but continued to support and facilitate the prescription changes thus making it responsible under the Code.

The options available were not simply limited, they were predominantly Chiesi products:

For changing patients from CFC-containing inhalers they listed only two pressurised MDIs and omitted all the other non-CFC containing devices. For those under 12 years, they solely advised the use of the Chiesi pMDI. As this was not a comprehensive range of treatments, it was inappropriate for Chiesi to facilitate this programme.

The therapeutic review of asthma patients on Seretide 125 MDI was described as one with the 'possibility of transfer to formoterol/beclomethasone (Fostair) MDI' and went on to describe Fostair as a cost-effective option to Seretide 125 MDI. For this to be a valid therapeutic review service, there must also be the 'possibility of transfer to' any one of a comprehensive range of other treatment options. The intention of the letter appeared to be to direct practices to change patients from Seretide 125 MDI to Fostair MDI as a cost-saving exercise, rather than one that was patient-led to ensure each individual received optimal treatment after appropriate clinical assessment.

The final area of prescribing covered in the letter was 'to optimise prescribing of tramadol m/r formulations to the local preferred option – Maxitram SR', a Chiesi product. There were numerous tramadol products available and other therapeutic options for the same indications. Chiesi's facilitation of this prescribing change, even if there was clinical assessment, was in breach of the Code as no other therapeutic options were to be considered.

Furthermore, GlaxoSmithKline considered that a *bona fide* therapeutic review should be closely aligned to best practice guidelines in a particular therapy area. Therefore a therapeutic asthma review should closely follow the British Thoracic Society/Scottish Intercollegiate Guidelines Network (BTS/SIGN) asthma guidelines, which were generally considered to represent best practice in asthma management. Patients who currently received Seretide 125 were already at step 3 (of 5) of these guidelines and had moderately severe disease which required careful clinical assessment to ensure optimal treatment of what was a potentially life-threatening condition. The guidelines stipulated that 'All people with asthma should have access to primary care services delivered by doctors and nurses with appropriate training in asthma management' and that in a structured review 'All patients should be reviewed regularly by a doctor or nurse with appropriate training in asthma management. The review should incorporate a written action plan'. The use of pharmacists to conduct the 'clinical assessment' of these patients was at odds with this recommendation as was the lack of any written action plan.

The guidelines also focussed on identifying patients whose asthma was under- or over-treated and increasing or decreasing their treatments in line with a well-defined treatment ladder. The Chiesi service, as described in the email, focussed solely on switching patients between different medicines on the same rung of the treatment ladder. Such switches were not recommended within the BTS/SIGN guidelines.

GlaxoSmithKline considered that Chiesi's admitted knowledge of the content of the email to practices from the local NHS meant it knew about the limited therapeutic options being recommended for its CSS

but continued to support and facilitate the prescription changes which thus made it responsible under the Code. GlaxoSmithKline also considered the clinical assessments carried out for moderately severe asthma patients were inadequate. Given these concerns, GlaxoSmithKline believed that Chiesi's CSS was a switch programme that failed to maintain high standards and might impact on patient safety and the reputation of the pharmaceutical industry in breach of Clauses 18.4, 9.1 and 2.

RESPONSE

Chiesi submitted that its CSS was a genuine therapeutic review service and not a switch service whereby a patient's medicine was simply changed to another without any clinical assessment.

In order to ensure the service complied with the Code all members of the CSS team who carried out therapeutic reviews were registered pharmacists who reported into a director who was also a registered pharmacist.

Therapeutic reviews were always done at the invitation and request of the GPs who decided which therapy areas should be reviewed and determined the medicines to be considered based on the comprehensive range available generally or from their own formulary. The CSS team did not influence, and was not permitted to be part of this decision making process. Once a GP had decided on a review, he/she could ask to be contacted by the CSS office if he/she wished to learn more about or potentially use the service. If the office agreed that Chiesi could support a particular request for a therapeutic review, in line with its standard operating procedure (SOPs), a CSS pharmacist would be allocated to undertake this review. In providing a therapeutic review, the pharmacist would operate under the written instructions of the GP. This written documentation explicitly detailed the therapy areas and medicine options the GP had selected.

Before any therapy review took place, the pharmacist would access individual patient records and clinically assess the full range of each patient's medicine and medicine history. As the recognised professional expert on medicines, the pharmacist did the following:

- Assessed each individual patient's medicine to ensure any therapy review requested and authorised by the GP was appropriate
- Checked for medicine interactions
- Checked for over or under ordering of medicines
- Checked for duplicate therapies
- Assessed compliance issues
- Assessed dosages and strengths to ensure they were correct
- Checked licensed indications
- Reviewed quantities issued and identified in-equivalence of quantities
- Checked all clinical investigations were up to date and identified tests overdue or not recorded
- Assessed potential side effects
- Assessed possible strength optimisation.

Chiesi noted that this was not an exhaustive list as different reviews might require additional considerations.

All clinical assessments, patient reviews and patient clinics were undertaken by the pharmacist on an individual patient basis, as detailed in the SOP. Any of the clinical queries or recommendations which emanated or resulted from these assessments, were detailed on a medicine query form and discussed and resolved at the end of each working day directly with the authorising GP. All individual patient reviews were signed off by the GPs, including any changes in treatment plans. As such, the GP retained full control of the review process, and the pharmacist worked under his/her instructions; the GP was fully responsible for any changes in individual treatment plans.

During inter-company dialogue GlaxoSmithKline did not appear to understand that Chiesi's pharmacists carried out a clinical assessment of the full range of each patient's medicine irrespective of therapy area. From its complaint, GlaxoSmithKline clearly believed that Chiesi's service was therapy area specific and the reviews were only focused on the medicines in the chosen therapy area. The therapy area determined by the GP was used to identify the cohort of patients who would be clinically assessed. The CSS pharmacist would then carry out a comprehensive therapeutic review of all the medicines for each patient irrespective of therapy area, as detailed above. This was why only pharmacists delivered the CSS therapeutic review service as they were the experts on medicines and the only health professional specifically qualified to provide a full therapeutic review across the patient's entire range of medicines. A complete review of a patient's full range of medicine enhanced patient care and benefitted the NHS; it improved the management of the patient's medical condition, improved health outcomes through optimal medicines use and reduced unwanted or unused medicines and thus reduced prescribing costs.

A clinical assessment by Chiesi's pharmacists did not always result in a change of the patient's medicine for a range of different clinical reasons and as outlined above, any clinical queries or recommendations which emanated or resulted from these assessments, were detailed on a medicine query form and discussed and resolved at the end of each working day directly with the authorising GP. Over the last two years no medicines had been changed in 45% of clinical assessments of patients by Chiesi's pharmacists.

Chiesi believed the service delivered by its pharmacists was a genuine therapeutic review which complied with the Code.

Chiesi noted that GlaxoSmithKline considered that

the service did not offer a comprehensive range of relevant treatment choices but was limited by the prescribing instructions given to practices by the local primary care pharmacy services.

Chiesi explained that the email was a confidential internal email from local health board to its practices stating its formulary choices, and Chiesi had neither input, nor any prior knowledge of its existence until it received a confidential copy from the local health board after it had been issued. Clearly Chiesi could not be held responsible for the contents of a third party document to which it had no input nor any prior knowledge of its content before circulation.

This email referred to specific Chiesi products; however Chiesi's CSS operated independently to any such specific local guidance. As detailed in Chiesi's CSS SOP, where the CSS was provided, then during the initial meeting between the GP and the CSS pharmacist, the GPs decided which therapy areas he/she would like reviewed and determined the medicines to be considered based on the comprehensive range of medicines which was available on the local formulary. The decisions regarding the therapy areas and range of medicines were those of the GPs themselves. The CSS pharmacist did not suggest to the GP which medicines should be considered. The GP could authorise any medicine(s) of their choice irrespective of any guidance from the local primary care organisation (PCO), such as provided in the email.

Chiesi believed its CSS offered a comprehensive range of relevant treatment choices and was not limited by the prescribing instructions given to practices by the local health board, in this instance, or any other such local prescribing guidelines. Each individual therapeutic review was determined by the authorizing GP at the outset. The service was not product specific and was not restricted to Chiesi's products.

Chiesi noted that GlaxoSmithKline considered that the clinical assessments carried out by the pharmacists were inadequate to ensure patient care was enhanced or maintained. In that regard Chiesi referred to the comprehensive clinical assessments outlined above.

In addition, in response to GlaxoSmithKline's concerns regarding a note-based review carried out by Chiesi's CSS, Chiesi clarified that its pharmacists could do either full patient-facing clinic reviews or note-based medicine reviews; SOPs existed for both types of review. As outlined above the GP controlled the review service and determined which type of review they required. Clearly in this case the GP required a note-based therapeutic review and this was performed as per the SOP provided. Chiesi's CSS offered both types of review and Chiesi acknowledged the benefits and the limitations each one could offer which was why the choice of review method was determined by the GP.

A note-based therapeutic review of the entire range of a patient's medicine with full access to the patient's medical history could deliver all the benefits already listed above, as the pharmacist could review all medicines in the context of the patient's medical condition, history and treatment. The main shortcoming of such a review was that the patient's treatment or dose might be changed without their direct involvement. For this reason an appropriate method of communicating any such changes was always agreed by the pharmacist with the GP and the patient was always given the opportunity to raise questions with the surgery. As well as raising any medicine queries directly with the GP at the end of each day, the pharmacist was also able to point out to the GP those patients they considered required a face-to-face consultation before any therapy change was made. Chiesi believed that such a review was in the interest of the patient as it was what their GP had determined was best for them, it benefitted the NHS and clearly a full review of the patient's medicine, even without the patient present, maintained and improved patient care in line with the Code.

A face-to-face review of the patient's medicine and condition allowed Chiesi's pharmacists to involve the patient as a full partner. Chiesi's pharmacists would listen to the patient's views about their medicines and take into account their preferences in any decisions about their treatment. A face-to-face review might be seen as the ideal as it provided an opportunity for a full concordant discussion about the patient's medicines, observations and counseling about the use of their medicines, such as inhaler technique, and recording of clinical measurements such as peak flow readings. A face-to-face review might be more likely to result in genuine agreement between the pharmacist and the patient, with the patient more likely to take their medicines as prescribed. However face-to-face medicine reviews did not always lead to a concordant discussion and they were more resource-intensive than a note-based review. In addition the GP might consider the previous surgery history of non-attendees at face-to-face clinics. A note-based review by a suitably qualified health professional's such as Chiesi's pharmacists might be preferable to no review which might be the outcome if only face-to-face clinics were adopted. All these were factors the GP might consider before finally choosing between a note-based or face-to-face review. Chiesi believed that both types of review enhanced and maintained patient care for the reasons outlined above and complied with the Code.

The Chiesi CSS was a non-promotional and non-product specific service. The team belonged to a non-promotional arm of the organization and was clearly de-lineated from the commercial part of the organization. The company also maintained a clear and distinct separation between the sales and service teams at all times and this was clearly defined with all Chiesi's SOPs. All members of the clinical support team were employees of Chiesi or external contractors employed by Chiesi to provide

the service operating under the management and SOPs of Chiesi. All members of the team who carried out therapeutic reviews were registered pharmacists and they reported into a director who was also a registered pharmacist. Before they carried out any therapeutic reviews the pharmacists were fully trained, and validated by the medical department, in the therapy areas and SOPs in which they would be working.

Chiesi's medical representatives were not involved in the therapeutic review process, except to sometimes, as a courtesy, to briefly introduce the clinical support pharmacist to the GP. The representative would then immediately leave the GP premises and would not return that day, or whilst the pharmacist was working within the practice. Any potential breach of the clear and distinct separation of sales and service by any member of staff, at any time, was considered a disciplinary offence as it would put the company in potential breach of the Code, and appropriate action was always taken by Chiesi's human resources department. If a representative received a request for a therapeutic review from a GP, he/she would refer the request to the clinical support office as outlined in their SOP.

Chiesi's CSS pharmacists were not bonused on sales, nor were they set targets based on patient numbers or product outcomes. This was a professional service provided by the company to deliver improved quality of care for patients and benefits to the NHS both of which enhanced the professional reputation of Chiesi with its customers.

Chiesi stated that all the documents provided which related to the CSS were strictly confidential as they would be of significant value and interest to third parties. Chiesi therefore requested that these were not disclosed to GlaxoSmithKline or any other party outside the PMCPA.

The Fostair SPC was provided and in the light of certain comments made by GlaxoSmithKline, Chiesi noted Section 4.1, Therapeutic indications:

Fostair is indicated in the regular treatment of asthma where use of a combination product (inhaled corticosteroid and long-acting beta2-agonist) is appropriate.
- patients not adequately controlled with inhaled corticosteroids and "as needed" inhaled short-acting beta2-agonist or
- patients already adequately controlled on both inhaled corticosteroids and long acting beta2-agonists.

Note: Fostair is not appropriate for treatment of acute asthma attacks.

In summary, Chiesi submitted that its CSS was a professional service delivered by registered pharmacists who were the recognised experts on medicines and the health professionals' best positioned to carry out full therapeutic reviews across a patient's full range of medicines. As such the Clinical Support Therapeutic Review Service was in the interests of the patients, delivered benefits to the NHS and enhanced patient care in line with the requirements of their GPs.

Chiesi was disappointed that GlaxoSmithKline did not recognise pharmacists as the health professionals who were the experts on medicines or consider that pharmacists were qualified to carry out clinical assessments as described, which put the company at odds with the NHS and fellow members of the ABPI.

Chiesi's CSS delivered a quality therapeutic review service, not a switch programme. The therapeutic review service maintained high professional standards at all times, it enhanced patient care and it enhanced the reputation of both Chiesi and the rest of the pharmaceutical industry. Chiesi believed this service complied with all aspects of the Code and it strongly refuted GlaxoSmithKline's allegations of breaches of Clauses 18.4, 9.1 and 2.

FURTHER RESPONSES

In response to a request for further information Chiesi stated that it had received a copy of the email on 26 April 2010. In response, Chiesi CSS emailed the local health board on the same day stating 'Thank you for the email. We will now start contacting practices to arrange appropriate appointments and will keep you updated in the usual manner'. As this email was received by the CSS Chiesi did not tell its sales representatives about it. A copy of the email and response from Chiesi was sent to the local clinical support pharmacist only.

In response to a question about how Chiesi understood the service would be introduced by the health board to its practices the company stated that, as outlined in the email from the local health board, the CSS had assisted the local NHS, under an arrangement akin to a joint working partnership, for a number of years and had completed several successful projects. For the patients the projects had resulted in better care and a better experience of the healthcare system. For the NHS the projects had resulted in better use of resources, greater value for money and lower costs and Chiesi had been able to assist the local NHS with faster implementation of policies which were relevant to the company's business. This was essentially in line with the ABPI guidance notes on joint working between pharmaceutical companies and the NHS and others for the benefit of patients (taking into consideration the 2008 ABPI Code of Practice for the pharmaceutical industry) produced in March 2009.

Previously, communication of the CSS by the health board to its practices had been by email and the CSS had then those practices directly to arrange appointments for Chiesi pharmacists to offer the service in line with Chiesi SOPs. From the dialogue between the CSS and the local health board, Chiesi expected the service would be introduced by the health board to its practices in the same manner.

Chiesi clarified that the local health board email was not sent to Chiesi for comment or approval before it was issued. The company had no input nor any prior knowledge of the email's existence until it received the confidential copy from the local health board on 26 April.

In response to a further request for information about what Chiesi understood the health board would tell practices about the service, Chiesi reproduced in full its comment above about joint working practices and previous email communication. In addition Chiesi stated that it also understood that the health board would advise its practices that they might use the CSS to undertake therapeutic reviews to assist them implement the local NHS clinical priorities or in any therapy areas which they believed would benefit patient care in their respective practices. Chiesi also understood that individual prescribers at these practices would decide whether to use the CSS and that the health board could not make the individual prescribers or practices use the CSS.

PANEL RULING

The Panel noted Chiesi's submission that the CSS had assisted the local NHS, under an arrangement akin to a joint working partnership, for a number of years. Chiesi had referred to the ABPI guidance notes on joint working between pharmaceutical companies and the NHS. In the Panel's view the CSS was service provision, not joint working. Joint working covered situations where, for the benefit of patients, the NHS and one or more pharmaceutical companies pooled skills, experience and/or resources with a shared commitment to successful delivery of patient centered projects. Each party had to make a significant contribution and outcomes had to be measured. Treatments must be in line with nationally accepted clinical guidance where such existed and the arrangements between the parties must be open and transparent.

The Panel noted that Clause 18.4 permitted the provision of medical and educational goods and services which enhanced patient care, or benefitted the NHS and maintained patient care. The supplementary information to Clause 18.4, Switch and Therapy Review Programmes, explained 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 any clinical assessment. Companies could promote a simple switch from one product to another but not assist in its implementation. A therapeutic review which aimed to ensure that patients received optimal treatment following clinical assessment was a legitimate activity for a pharmaceutical company to support or assist. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds. The Panel noted that GlaxoSmithKline had alleged that the current service, a review based on patients' medical records, was insufficient to enhance patient care or benefit the NHS and maintain patient care.

The Clinical Support Service Protocol (CHCS520100215), dated April 2010, explained that the service would enable PCOs and individual practices to carry out clinical assessments and therapeutic reviews of specific patient groups. The service was non promotional and non product specific. The GP retained full control of the process at all times.

The SOP Procedure for Asthma Therapeutic Review (CL002) dated 4 August 2010, began by referring to asthma control and the BTS/SIGN guidelines 2008. The introduction stated that when deemed necessary, an asthma clinic could be used to optimise patients' asthma control and provide reinforcement and education on the importance and achievability of good asthma control and hence improve quality of life. Section 2 stated that the CSS pharmacist would clarify with the GP whether the review was conducted with or without the patient. Factors which determined this included whether after clinical assessment any potential changes to a patient's asthma treatment might result in a change of molecule or device but would ultimately be determined by the GP's instructions. If the GP chose a paper review the Asthma Therapeutic Review Authorization Form (Non-Clinic) (CHCSS20100304 – June 2010) would be completed and identify: which patient groups should be reviewed; what the GP's treatments of choice were; which strengths should be used and any special instructions. The form stated that patients would be reviewed in accordance with BTS and National Institute for health and Clinical Excellence (NICE) Guidelines. Products were listed beneath the following headings: short-acting beta2 agonists, long acting beta2 agonists, inhaled corticosteroids, fixed inhaled corticosteroids/long-acting beta-agonist (ICS/LABA) combinations and others.

The Therapeutic Review Project Specification Form (CHCSS20100129) set out the services to be provided to the GP practice and the terms of service of a patient record review. It was noted that the result of a clinical assessment might require a face-to-face clinical assessment, possible changes in treatment including changes of dose, medicine or cessation of treatment. No medicines would be changed unless authorized by the GP or if, in the clinical judgement of the pharmacist, there was a query which required resolution or discussion by or with the GP. The GP and pharmacist would meet at the end of each working day and at the end of the review so, *inter alia*, the GP could summarize the completed work and authorize any further actions required. The authorizing GP was asked to sign each page of the patient lists to indicate that they were 'fully happy' with the action taken.

The SOP Procedure for Asthma Therapeutic Review (CL002) detailed how to conduct the search on a practice computer. A clinical rationale for any medicine change should be recorded. At the end of

the day the SOP mandated a further meeting with the GP to appraise them of the work carried out, sign off any treatment changes made and to address any queries. The SOP was supported by a training document SOP for pharmacists (CHCSS20100416 – August 2010) which stated that it would be usual to see the patients in a clinic setting unless the GP stipulated otherwise. The Clinical/Medication Query Form recorded any patient specific queries to be discussed with the GP.

The Panel noted that GlaxoSmithKline had provided a patient letter dated 5 October 2009 to support its allegations about the current service. The Panel noted that the SOP contemporaneous to the patient letter appeared to describe a different service, it was dated 2 April 2009 and bore the reference CL001. It described a review based on clinical assessment of a patient's records alone. There was no reference to a patient clinic. The GP authorized each step. The Panel did not have all the documentation for this review but considered that GlaxoSmithKline had not made specific allegations about it. In the Panel's view, the only issue to consider was whether a medical record review was adequate to, *inter alia*, enhance or maintain patient care.

The Panel noted that Thomas *et al* was a 2 year retrospective matched cohort study which evaluated the impact on asthma control of inhaler device switching without an accompanying consultation in general practice and determined that such a switch was associated with worsening asthma control. Doyle *et al* undertook qualitative interviews with 19 asthma patients who had experienced a non-consented switch of their inhaler device and concluded that such switches may, *inter alia*, diminish self-control associated with good asthma management. The Panel noted that there was some evidence in relation to changing a patient's device without consent. No clinical evidence had been submitted in relation to other changes such as a change in molecule, dose, etc. The Panel noted, however, that the CSS, based on patients' records, could potentially involve a change of device.

The Panel noted GlaxoSmithKline further considered that a *bona fide* therapeutic review should be closely aligned to BTS/SIGN best practice guidelines. As an example GlaxoSmithKline noted that moderately severe asthmatics on Seretide 125 were already at step 3 (of 5) of the BTS guidelines and required careful clinical assessment. The guidelines referred to access to primary care services delivered by doctors and nurses with appropriate training in asthma management and GlaxoSmithKline alleged that the use of pharmacists was at odds with this recommendation as was any written action plan. The Panel noted the BTS/SIGN guidelines and reference to clinical review by a nurse or doctor. The Panel noted that the guidelines were referred to in the introduction to the current SOP. The Panel did not consider that a medical record review by a pharmacist as part of the CSS meant that ongoing clinical care from a nurse or doctor was in any way precluded as implied by GlaxoSmithKline.

The Panel noted the SOP training document for pharmacists. The decision to have a medical notes review or clinic was taken by the authorizing GP. The SOP Procedure for Asthma Therapeutic Review and the SOP Training Document for Pharmacists made it clear that in some circumstances a clinic review might be preferable.

The authorizing GP defined the scope of the review, identified appropriate patients and had the final word on all matters in relation to it including product changes. In such circumstances the Panel did not consider that on the information before it about the current service a review of patients' records by a pharmacist in principle failed to enhance patient care or benefit the NHS and maintain patient care as alleged. No breach of Clauses 9.1 and 18.4 were ruled. The Panel consequently ruled no breach of Clause 2.

The Panel noted the requirements of Clause 18.4 and its supplementary information. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non medicinal choices and should not be limited to the medicines of the sponsoring pharmaceutical company. The Panel noted that the email from the local NHS primary care pharmacy services encouraged practices to take up the assistance of the CSS to complete the three tasks outlined in the email. The first task was to review patients using CFC containing beclometasone inhalers and transfer them to CFC-free inhalers. The local formulary options were listed – Clenil modulite or Qvar for adults over 12 and Clenil Modulite for children. The second review was of Seretide 125 MDI patients with a possibility of transfer to Fostair MDI which was described as a local formulary option and a cost effective alternative to Seretide 125 MDI. The final option described assistance to optimize the prescribing of tramadol to the formulary preferred option of Maxitram SR.

The Panel noted that the copy of the email provided in Chiesi's response was the second page of a two page email which bore the date, beneath the text, of 28 April. Chiesi submitted that it received the email on 26 April. This discrepancy was explained in intercompany dialogue. Chiesi had not supplied a version of the email that it had received. It appeared that the only meaningful difference between the two versions was the date.

The Panel accepted, in general, that when *bona fide* therapeutic reviews were offered to practices the prescriber would, nonetheless, be aware which products were on the local formulary and he/she may decide, as a result of the review, that such products were suitable therapeutic options. However, in the view of the Panel, the content of the service and way it was offered must comply with the Code. Irrespective of what products were on the local formulary the review must offer the prescriber a comprehensive range of treatment choices. Pharmaceutical company assistance in the implementation of a switch service was unacceptable.

In the view of the Panel the email to practices from the local primary care pharmacy services was such that the prescriber's choice was, in effect, restricted to switching to those products mentioned therein. Practices would attach the greatest weight to the email. It was entirely unclear from Chiesi's responses what it knew about how the service would be introduced to local practices at the outset by the local health board other than such instruction would be by email. The Panel considered that on receipt of a copy of the email Chiesi knew that the local primary care pharmacy services was encouraging GPs to use its CS service in a way that rendered its provision in breach of the Code. That the email was sent independently and that Chiesi submitted that it had no prior knowledge of its content before it received a confidential copy was irrelevant. Once Chiesi knew about the email then it also knew that GPs were being encouraged to use the CS service to effect a switch programme. This was compounded by the wholly unacceptable provision by Chiesi of the email and the company's response to the local CSS pharmacist. The Panel had not seen the covering email provided to the local CSS pharmacist. Nonetheless it appeared that the local CSS pharmacist might have in effect been instructed to implement a switch service. Overall, the Panel considered that the arrangements did not meet the requirements of Clause 18.4 and a breach of that clause was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel considered that the provision of a switch service brought discredit upon, and reduced confidence in, the pharmaceutical industry. A breach of Clause 2 was ruled.

APPEAL BY CHIESI

Chiesi submitted its CSS was in line with its comprehensive SOPs, training documents and associated approved CSS documents and was not a switch programme nor a switch service as ruled by the Panel. The SOPs were robust and independent of any third party recommendations. The CSS pharmacists were professional experts on medicines and the only health professional specifically qualified to provide a full therapeutic review across the patient's entire range of medicines. As registered pharmacists they had to comply with their own professional Code of Ethics which ensured the highest standards were always maintained. Chiesi appealed the ruling of a breach of Clause 9.1. The clinical assessments performed by the CSS pharmacists were thorough, offered a comprehensive range of relevant treatment choices and the provision of the service should not be judged on the contents of a third party email in isolation. The service provided transparent benefits to patients and the NHS. Chiesi submitted that the provision of its CSS in the local NHS, irrespective of the contents of the third party email, complied with Clause 18.4 and its supplementary information.

Chiesi submitted that its pharmacists took great pride in delivering enhanced quality of care to patients and the NHS. Regular positive feedback from GPs indicated their appreciation of the service and highlighted how it had delivered improved quality of care for their patients. This enhanced the reputations of Chiesi and the pharmaceutical industry. The CSS delivered in the local NHS was provided in a professional manner which reflected very positively on the industry and Chiesi did not believe, irrespective of any other ruling, that the service had brought discredit upon, or reduced confidence in, the pharmaceutical industry. Chiesi appealed the ruling of a breach of Clause 2.

Chiesi confirmed that it had received a copy of the email from the local NHS primary care pharmacy services on 26 April and that the contents were the same as provided by GlaxoSmithKline. The only dispute regarding this email was the inclusion of the date of '28th April' and the reference 'page 2 of 2', and this matter was clarified during inter-company correspondence. Chiesi had never disputed the contents as written by the local NHS primary care pharmacy services. Chiesi noted the Panel's concern that it did not provide a copy of the email it received on 26 April, however Chiesi was bound by the local NHS confidentiality and disclaimer notice attached to its copy and the Panel already had the full contents of the undisputed email from GlaxoSmithKline.

Chiesi noted the Panel's comment that it 'had not seen the covering email provided to the local CSS pharmacist. Nonetheless it appeared the local CSS pharmacist might have in effect been instructed to implement a switch service'. Chiesi submitted that the local CSS pharmacist was only copied on its email response of 26 April to the local NHS and this contained the original local NHS email as outlined in its response above. There was no covering email provided to the local CSS pharmacist and there were no instructions given to the local CSS pharmacist to implement a switch service.

Chiesi submitted that its CSS pharmacists were trained to comply with the SOPs and training documents submitted previously. A CSS pharmacist would never be instructed to implement a switch service as was alleged in the Panel ruling.

Chiesi noted the Panel's view that 'the email to practices from the local primary care pharmacy services was such that the prescribers' choice was, in effect, restricted to switching to those products mentioned therein. Practices would attach the greatest weight to the email'. Chiesi submitted that the email from the local NHS was sent directly to practice managers and not to GPs/prescribers. If the prescribing GP had not seen the email then his prescribing choice could not be restricted in the manner suggested. If the GP had seen the email, then as a self employed contractor to the NHS, and not an employee of the Health board, he would not be obliged to follow the guidance provided therein. Within primary care GPs had responsibility to improve patients' quality of care, expand the range of service to patients and to improve the working conditions for staff. GPs were responsible for prescribing as they considered appropriate for each patient. The health board might issue prescribing

guidance, such as in the email, but GPs were not obliged or contracted to follow such guidance and were free to make the prescribing decisions appropriate for each patient. Within the CSS the authorising GP, not the health board, determined any medicine changes. The Therapeutic Review Authorization forms which must be completed by GPs were blank and the GPs must determine their own treatment of choice in their own handwriting. GPs had absolute freedom to authorize any medicine(s) of their choice irrespective of any guidance from their health board and therefore the service allowed GP's a comprehensive range of treatment choices.

Chiesi submitted that the Panel's comment that 'Practices would attach the greatest weight to the email' was unsubstantiated, did not reference the prescriber or acknowledge the GPs' independence to prescribe. The CSS was delivered independently to any weight which might have been attached to the email by the practice, and allowed GPs a comprehensive range of treatment choices.

Chiesi noted that in its ruling the Panel 'considered that on receipt of the copy of the email Chiesi knew the local primary care pharmacy services was encouraging GPs to use its CS service in a way that rendered its provision in breach of the Code. That the email was sent independently and that Chiesi submitted that it had no prior knowledge of its content before it received a confidential copy was irrelevant. Once Chiesi knew about the email then it also knew that GPs were being encouraged to use the CS service to effect a switch programme'. Chiesi fully acknowledged the statement in the Panel's ruling that it operated the CSS in the full knowledge of the contents of the local NHS email as it believed the CSS delivered a genuine therapeutic review service provided in compliance with Clause 18.4.

As stated above, the local NHS email was sent to practice managers and so did not encourage GPs to use the CSS in a way that rendered its provision in breach of the Code, as it was not sent to them. The CSS was only authorized by GPs and not practice managers.

Chiesi noted that the Panel appeared to have ruled that the CSS provided a switch service based upon the contents of the third party email alone and not based upon how the CSS was actually delivered. The Panel did not refer to any of the comprehensive SOPs, training documents or any of the detailed explanation of the service provided in Chiesi's response. The CSS was always delivered in compliance with the SOPs and complied with all aspects of the Code. The service was not delivered nor amended to meet the stipulations of any third party email as had been ruled. For each of the three services outlined by the local NHS in its email, Chiesi submitted that it fully outlined below why it believed that the CSS provided complied with aspects of Clause 18.4 and its supplementary information.

Chiesi noted the three service reviews outlined in the local NHS email.

Chiesi noted 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. For example it would be unacceptable if patients on medicine A were changed to medicine B, without any clinical assessment, at the expense of a pharmaceutical company promoting either or both medicines. It would be acceptable for a company to promote a simple switch from one product to another but not to assist a health professional in implementing that switch even if assistance was by means of a third party such as a sponsored nurse or similar. Such arrangements were seen as companies in effect paying for prescriptions and were unacceptable.

Chiesi submitted that the three therapeutic reviews were delivered by the CSS pharmacist who used the relevant SOP. The GP had to complete the relevant therapeutic review authorization form which was blank to allow him to state his treatments of choice in all classes of therapy irrespective of the guidance provided by the health board in the email. No medicine was simply changed to another without a clinical assessment.

The CSS pharmacist made a clinical assessment of each individual medicine of each individual patient in the patient cohort specified by the GP. This assessment was not limited to beclometasone or salmeterol/fluticasone medicines or tramadol modified release (according to the review being undertaken) but included a clinical assessment of each medicine currently prescribed for that patient. The CSS pharmacist assessed and recorded the following general points for discussion with the GP at the end of the day:

- interactions
- over/under ordering
- duplicate therapy
- compliance
- dosage
- strength
- licensed indication
- item on repeat not issued for 12 months
- quantities issued
- clinical investigation – tests overdue or results not recorded
- inequivalence of quantities eg 28 and 30 days supplies on same prescription
- side effects
- strength optimisation.

Chiesi submitted that a therapeutic review was different to a switch service. A therapeutic review service, which aimed to ensure that patients received optimal treatment following a clinical assessment, was a legitimate activity for a pharmaceutical company to support and/or assist. The CSS provided a therapeutic review service and not a switch service as ruled. This service ensured each patient received optimal treatment following the clinical assessment of each medicine they were prescribed. Chiesi submitted that this was a legitimate activity for it to support.

Chiesi submitted that the results of such clinical assessments might require, *inter alia*, changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The results of the clinical assessments of each individual medicine of each individual patient within the therapeutic reviews might have included a number of outcomes. Chiesi gave comprehensive details of some of the changes in medicine which might have occurred. Some of the possible changes involved the prescription of other companies' medicines.

Chiesi submitted that as a result of these clinical assessments its CSS delivered a genuine therapeutic review which included a comprehensive range of relevant treatment choices, including non-medical choices, for the GP and these were not limited to Chiesi's products. Chiesi noted that in order to maintain patients on CFC-containing beclometasone on the same device, the only two CFC-free treatments available were Clenil Modulite (Chiesi) and Qvar (Teva), as outlined in the email.

Chiesi noted that the arrangements for a therapeutic review must enhance patient care, or benefit the NHS and maintain patient care, and must otherwise be in accordance with Clause 18.4 and the supplementary information on the provision of medical and educational goods and services.

Chiesi submitted that with regard to the second of the three services outlined in the local NHS email, a computer-based therapeutic review of the entire range of a patient's medicines with full access to the patient's medical history delivered all the benefits already listed above, as the pharmacist reviewed all medicines in the context of the patient's medical condition, history and treatment. During a computer-based therapeutic review, the patient's treatment or dose was changed without their direct involvement. For this reason an appropriate method of communicating for all changes was agreed by the CSS pharmacist with the GP and the patient was always able to raise questions with the surgery. As well as raising any medicine queries directly with the GP at the end of each day, the pharmacist was also able to bring to the attention of the GP any patients they considered required a face-to-face consultation before changes were made. As acknowledged by the Panel in its ruling, 'The authorising GP defined the scope of the review, identified appropriate patients and had the final word on all matters in relation to it including product changes'. Chiesi further submitted that a face-to-face clinic review of the patient's medicine and condition allowed the CSS pharmacist to involve the patient as a full partner, provided an opportunity for a full concordant discussion about the patient's medicines, allowed for observations and counselling about the use of their medicines, such as inhaler technique, and allowed clinical measurements such as peak flow to be recorded.

Either type of review, computer based or face-to-face, was in the patient's interest as it was what their GP had determined was best for them, benefitted the NHS and maintained and improved patient care in compliance with Clause 18.4.

Chiesi submitted that the full clinical assessment of each patient's individual medicine delivered by the CSS pharmacist as part of the therapeutic review service and as outlined above clearly enhanced patient care as it optimised their treatment and improved patient safety and adherence. In addition the clinical assessments provided by the CSS clearly benefitted the NHS for the reasons stated. The therapeutic review service was delivered in accordance with Clause 18.4 and the supplementary information on the provision of medical and educational goods and services as outlined.

Chiesi submitted that the decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change a patient's treatment must be documented with evidence that it was made on rational grounds.

Chiesi submitted that the CSS pharmacist carried out either a full patient-facing clinic review or computer-based therapeutic reviews as per the relevant SOP which stated:

'If any of the patient's asthma medication has been changed this should be recorded clearly on the patient cohort lists against the relevant name and a clinical rationale for the change must be annotated.'

'Once all patients have been clinically assessed, the CSS Pharmacist must meet again with the GP to go through the patient lists. He/she must sign each page of the patient lists to indicate that they are happy with the action taken and that it meets with their approval. Any queries noted on the Clinical/Medication Query Form must also be addressed and actioned according to the GP's wishes.'

Finally Chiesi noted the concerns raised by the Panel regarding the job description for the CSS pharmacists and the competencies required as defined within the job descriptions. Chiesi submitted that this was a non-promotional role and it would make the necessary representations to the Panel to explain how these competencies fitted within its own internal competency framework and the non-promotional role of the CSS pharmacist. This would be taken up with the Director of the PMCPA outside the scope of this appeal.

COMMENTS FROM GLAXOSMITHKLINE

GlaxoSmithKline agreed with the Panel that the activities carried out by and on behalf of Chiesi in the local area in late 2009 and early 2010 constituted the unacceptable practice of a company knowingly supporting an activity where patients would be screened and, on the basis of their receiving certain medicines, switched to one of a limited list of alternatives.

GlaxoSmithKline alleged that the two letters provided as part of its complaint clearly demonstrated Chiesi's support for:

1 A service which resulted in a letter informing a patient that their medicine was being switched from Seretide to Fostair. There did not appear to have been anything resembling a clinical assessment underlying this change and the patient was informed that the change of medicine was supported by Chiesi.

2 A service which provided assistance to primary care practices, covering three therapy areas where switching to alternative, Chiesi, medicines was advised. This service was described in a letter from the health board to a GP practice manager together with a summary of the medicines to be switched. The practice was asked to take advantage of the service offered by Chiesi.

GlaxoSmithKline alleged that irrespective of the intention of the service offered by Chiesi and the SOPs provided, Chiesi's provision of a therapy review service in the local area, where it knew that guidance would result in the identification of patients on certain medicines, with a view to switch them to alternatives supplied by Chiesi, was unacceptable. GlaxoSmithKline acknowledged that the guidance was provided by NHS staff and that the GP would retain final responsibility for prescribing choices. However, Chiesi failed in its responsibility to abide by the letter and spirit of the Code and by doing so, had breached the Code and misled health professionals as to what constituted good practice within the pharmaceutical industry.

GlaxoSmithKline stated that the SOPs provided by Chiesi (Asthma Therapeutic Review CHCSS20100515, August 2010 and Therapeutic review CHCSS20090280 Nov 2009) outlined a very robust process for the conduct of therapy reviews by the CSS pharmacists. GlaxoSmithKline assumed policies in place at the time of initiation of Chiesi's support were in line with the SOPs above.

GlaxoSmithKline stated that Chiesi cited these SOPs as evidence that the services provided in the local area did not breach the Code. However, GlaxoSmithKline's complaint did not relate to these documents. GlaxoSmithKline believed that implementing the services outlined within the SOPs with knowledge of and in support of the therapy switching objectives of the local NHS was clearly in breach of the Code.

As part of its appeal, Chiesi had also cited the professional responsibilities of pharmacists and GPs together with an argument that the advice was not issued directly to the GP as a reason why it was not in breach of Clauses 18.4, 9.1 and 2. GlaxoSmithKline alleged that citing the professional abilities and Code of Ethics of the Chiesi CSS pharmacists, or arguing that the guidance email from the local health board was sent to practice managers and not to GPs, who would be free to make their own treatment decisions rather than following the advice issued, was irrelevant and demonstrated that Chiesi did not understand its responsibilities and as such had acted in a way to damage its reputation and that of the industry in general.

Chiesi went on to state that even if GPs knew about the advice issued by the health board, they did not need to follow it. GlaxoSmithKline alleged that this further reflected Chiesi's lack of responsibility for its involvement in the switch service and also showed a lack of regard and/or insight into how the NHS operated.

GlaxoSmithKline was confident that the services outlined in the SOPs could be implemented by Chiesi in a way that benefitted patients and the NHS and complied with the Code. However, in this case, Chiesi had failed in its responsibility to ensure that its services were provided in a compliant way.

Despite Chiesi's reasons for appeal, GlaxoSmithKline continued to allege that in its provision of support in the local NHS, Chiesi had breached Clauses 18.4, 9.1 and 2 of the Code.

APPEAL BOARD RULING

The Appeal Board noted that the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated that switch services paid for or facilitated directly or indirectly by a pharmaceutical company were prohibited. A therapy review service which aimed to ensure that patients received optimal treatment following a clinical assessment was a legitimate activity for a pharmaceutical company to support and/or assist. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non medicinal choices and should not be limited to the medicines of the sponsoring pharmaceutical company.

The Appeal Board noted that the local NHS email informed the reader that they might be contacted by [Chiesi] and that the company could provide support to assist with a number of actions on prescribing which were relevant to the local NHS. In particular, practices were encouraged to take up the assistance of the CSS to complete the three tasks outlined. The first task was to review patients using CFC-containing beclometasone inhalers and transfer them to CFC-free inhalers. The local formulary options listed were Clenil Modulite or Qvar for adults and children over 12 and Clenil Modulite for children. The second review was of Seretide 125 MDI patients with a possibility of transfer to Fostair MDI which was described as a local formulary option and a cost effective alternative. The final task listed was to seek assistance to optimize the prescribing of tramadol modified release formulations to the formulary preferred option of Maxitram SR.

The Appeal Board noted that upon receipt of a copy of the email Chiesi responded by stating 'Thank you

for the email. We will now start contacting practices to arrange appropriate appointments and will keep you updated in the usual manner'. The Appeal Board was extremely concerned that Chiesi's response showed that the company intended to act proactively to assist in the implementation of the local NHS' prescribing plans as outlined in the email. A copy of the email and Chiesi's response was sent to the local CSS pharmacist and, in the Appeal Board's view, would inevitably influence his/her interactions with local practices.

The Appeal Board considered that the email from the local NHS was, in effect, advice from the local primary care organization that certain patients should be switched to certain Chiesi products. Such advice would be influential; in the Appeal Board's view prescribers would need good reasons not to follow it. The Appeal Board considered that Chiesi was naive to state that because the email was sent to practice managers and not to GPs the GPs would not be influenced by it; practice managers were bound to discuss the email with them. The Appeal Board considered that pharmaceutical company assistance in the implementation of the switch services detailed in the email was unacceptable.

Overall, the Appeal Board considered that Chiesi's role in supporting the implementation of the local NHS advice did not meet the requirements of Clause 18.4 and it upheld the Panel's ruling of a breach of that clause. High standards had not been maintained and the Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The Appeal Board considered that changing a patient's medicine was an extremely sensitive situation and the utmost care was needed. The provision of a switch service brought discredit upon, and reduced confidence in, the pharmaceutical industry and the Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on all points was unsuccessful.

Complaint received **20 August 2010**

Case completed **28 February 2011**