ANONYMOUS MEMBER OF A PRIMARY CARE TRUST MEDICINES MANAGEMENT TEAM v TRINITY-CHIESI

Therapeutic review service

An anonymous member of a primary care trust (PCT) medicines management team complained that a programme being run by Trinity-Chiesi in one of the complainant's practices, which advocated a switch from beclometasone CFC and beclometasone CFC-free to its branded beclometasone CFC-free product, Clenil, was in breach of the Code. The complainant noted that the Code prohibited pharmaceutical companies from sponsoring switch services.

The Panel noted that 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 were prohibited. Companies could promote a simple switch from one product to another but not assist in its implementation.

The Panel noted that the complainant had made a very broad allegation but no details had been provided. The complainant was anonymous and non-contactable.

The Panel noted that a document headed 'Prescribing Review Service – Protocol' stated that the service, provided by Trinity-Chiesi's Clinical Support Services (CSS) team, was not linked to the use of any particular products. Briefing material for the representatives clearly explained that the Code prohibited a pharmaceutical company from assisting a health professional with a switch programme. Representatives were thus told that they could not provide any support for a health professional to switch a patient's medicine simply to Trinity-Chiesi's products, although the health professionals were free to do this without support if they wished. The service could only be offered to a practice which required support to undertake a therapeutic review which was a review of patient management which aimed to ensure that patients received optimal treatment following a clinical assessment. There were no criteria listed in the documents as the basis for deciding when patients were not receiving optimal treatment. This was reinforced by the preprinted Respiratory Review Authorization Form for completion by the GP. The form listed a number of medications, for example 'all beclometasone pmdis', with details of the doses and then a section beneath the heading 'Treatment of choice' which was left blank for the GP to complete as was a box beneath the heading 'Special conditions/patient specific directions'.

The Panel also noted from other documents supplied that the representatives had no input into the service other than to introduce the service to GPs and liaise between the parties in the early stages to ensure that appointments for CSS pharmacists to go to the practices were made. There was to be little contact between the CSS pharmacist and the representatives although the representatives were expected to meet the CSS pharmacists on their first visit to any surgery to introduce them to the practice staff. No reference to the service being provided or to any Trinity-Chiesi products was to be made at that introductory meeting. Once the CSS pharmacist had been introduced the representative had to leave the surgery.

The Panel noted that the CSS pharmacist and the GP decided which patients to review. Patients were not clinically assessed in person but their individual medical records were reviewed. Any medication changes were noted together with the rationale for such. At the end of the day the authorizing GP had to go through the patient lists generated by the CSS pharmacist and approve all the changes made. The Panel was concerned that medication changes were made by the CSS pharmacist and these were then authorized at the end of the day by the GP even though the meeting at the start of the day would give the CSS pharmacist clear direction of the GPs wishes. The Medication Summary Form stated that the form was a breakdown of the patient numbers on each of the strengths of branded/generic medication that the GP asked the CSS pharmacist to review. It appeared that the review was product led rather than patient led. However patients taking asthma medication would have to be moved to a CFC free medication due to the non availability of CFC containing medication.

The Panel was concerned that some examples of patient letters which had been provided appeared to indicate that it was anticipated that as a result of the CSS patients would be changed onto Trinity-Chiesi's product Clenil Modulite. Nonetheless the Panel considered, on the basis of the information before it, that there was no evidence to show that the CSS acted as a switch service whereby patients were simply switched from one product to another without clinical review. No breach of the Code was ruled.

An anonymous member of a primary care trust (PCT) medicines management team complained about the promotion of Clenil (CFC-free beclometasone) by Trinity-Chiesi Pharmaceuticals Ltd.

COMPLAINT

The complainant had recently been made aware of a

programme being run by Trinity-Chiesi in one of the complainant's practices, which advocated a switch from beclometasone CFC and beclometasone CFC-free to its branded beclometasone CFC-free product, Clenil.

The complainant alleged that this was in breach of Clauses 18.1 and 18.4 of the Code which prohibited switch services paid for and facilitated by the sponsor of the service, Trinity-Chiesi.

When writing to Trinity-Chiesi, the Authority asked it to respond in relation to Clauses 2 and 9.1, as well as Clauses 18.1 and 18.4 referred to by the complainant.

RESPONSE

Trinity-Chiesi stated that it did not operate a switch service for Clenil and as such was unable to respond to the complaint. Following a request from the Panel for information about the services Trinity-Chiesi did provide, the company supplied details about a non-promotional therapeutic review service called the Clinical Support Service (CSS). Trinity-Chiesi noted that the complainant had not complained about the CSS. However, as requested, it would provide the relevant documents pertaining to this service.

The CSS was provided by registered pharmacists who under written instructions from the authorising GP would access individual patient records and carry out a full clinical assessment of each patient's therapy prior to any therapeutic review taking place. The clinical assessments made by the pharmacist, as the recognised professional expert on medicines, included:

- Assessment of each individual patient's medication to ensure any therapeutic review requested and authorised by the GP was appropriate for that patient
- Checking for medication interactions
- Checking for over or under ordering of medicines
- Checking for duplicate therapies
- Assessment of compliance issues
- Checking dosages and strengths were correct
- Checking licensed indications
- Reviewing quantities issued and identifying in-equivalence of quantities
- Checking all clinical investigations were up to date and identifying tests overdue or not recorded
- Assessment of potential side effects
- Assessment of possible strength optimisation

Any of the clinical queries or recommendations emanating or resulting from these assessments, would be detailed on a medication query form and discussed and resolved directly with the authorising GP.

Trinity-Chiesi believed that this non-promotional therapeutic review service complied with the Code and in particular with Clauses 18.1 and 18.4.

Trinity-Chiesi provided copies of the CSS documents which related to the prescribing of beclometasone (with or without CFC). Trinity-Chiesi did not have any service documents which related specifically to the prescribing of Clenil as this was not a product-specific service offering.

In response to a request for further information, Trinity-Chiesi explained that the CSS pharmacist would meet with the authorising GP at the start of the day to agree the therapy reviews which were required. This was documented on the Respiratory Review Authorisation form (TRCSS20070194).

The CSS pharmacist would produce a list of patient cohorts in line with these requirements ready for clinical assessment.

The CSS pharmacist would perform the therapeutic review and clinically assess the therapy of each individual patient. If any changes to therapy were made this was clearly recorded on the patient cohorts list against the relevant individual name and a clinical rationale for the change was annotated by the CSS pharmacist. If a patient was clinically assessed but their therapy was not changed the CSS pharmacist would score through their name on the list and clearly annotate the rationale for this. Whilst any changes to therapy were made at this point, they were only finalised once they had been approved in writing by the GP at the end of the day.

The CSS pharmacist would also Read Code any change to the patients' therapy on the patient records on the GP computer system, detailing the action taken and the date it was done. The rationale for any change made would also be added alongside the Read Code (ie medication changed under direction from Doctor X as part of the transition to CFC-free inhalers).

The CSS pharmacist would meet with the GP at the end of each day in surgery to go through the patient lists. The GP must review the individual patients and the accompanying rationale for change which had been stated by the CSS pharmacist on the lists. The GP must sign each page of the lists to indicate they were happy with the actions taken and they met with their approval. Any clinical queries or recommendations emanating or resulting from the clinical assessments would be detailed on the Medication Review Query forms (TRCSS20070196) and discussed and resolved directly with the GP at this meeting. Any further actions requested by the GP during the meeting were then undertaken by the CSS pharmacist before leaving the surgery.

The process clearly met the requirements of the Code as the decision to change or commence treatment for each individual patient was clearly made and authorised by the prescribing GP and supported by the written evidence on the patient lists which were stored securely within the surgery where the clinical work had taken place. The CSS pharmacist clearly documented the evidence that any changes were made on rational grounds both on the patient lists and on the patients' computer records.

The clinical assessments made by the pharmacists, as the recognised professional experts on medicines, was made using the individual patient records within the surgery.

There were no pre-determined expectations of how many patients a CSS pharmacist would review in a day. There were many variable factors which influenced the time it took to conduct a clinical assessment of each individual patient's medication, such as the number, and complexity, of each individual patient's medication, the availability of the GP during the working day and the type of computer system in the surgery, for any expectation to be set as to the number of reviews to be completed in a day.

Trinity-Chiesi stated that its objective during each review was to ensure the highest level of professional service was delivered to the GP and the patient irrespective of the amount of time taken.

PANEL RULING

The Panel noted that the supplementary information to Clause 18.4, Switch and Therapy Review Programmes, stated, *inter alia*, that Clause 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 that the complainant had made a very broad allegation that Trinity-Chiesi's programme being run in one of the complainant's practices which advocated a switch to Clenil was in breach of Clauses 18.1 and 18.4. No details had been provided. The complainant was anonymous and non-contactable.

The Panel noted that a document headed 'Prescribing Review Service – Protocol' stated the service, provided by the CSS team, was not linked to the use of any particular products. Briefing material for the representatives clearly explained that the Code prohibited a pharmaceutical company from assisting a health professional with a switch programme. Representatives were thus told that they could not provide any support for a health professional to switch a patient's medicine simply to Trinity-Chiesi's products, although the health professionals were free to do this without support if they wished. The service could only be offered to a practice which required support to undertake a therapeutic review which was a review of patient management which aimed to ensure that patients received optimal treatment following a clinical assessment. There were no criteria listed in the documents as the basis for deciding when patients were not receiving optimal treatment. This was reinforced by the preprinted Respiratory Review Authorization Form (TRCSS20070194) for completion by the GP. The form listed a number of medications, for example 'all beclometasone pmdis', with details of the doses and then a section beneath the heading 'Treatment of choice' which was left blank for the GP to complete as was a box beneath the heading 'Special conditions/patient specific directions'.

The Panel also noted from other documents supplied, that the representatives had no input into the service other than to introduce the service to GPs and liaise between the parties in the early stages to ensure that appointments for CSS pharmacists to go to the practices were made. There was to be little contact between the CSS pharmacist and the representatives although the representatives were expected to meet the CSS pharmacists on their first visit to any surgery to introduce them to the practice staff. No reference to the service being provided or to any Trinity-Chiesi products was to be made at that introductory meeting. Once the CSS pharmacist had been introduced the representative had to leave the surgery.

The Panel noted that the CSS pharmacist and the GP decided which patients to review. Once the patient cohort had been identified the CSS pharmacist reviewed individual patient records to assess interactions/compliance/duplicate therapies etc. Patients were not clinically assessed in person but their individual medical records were reviewed. Any medication changes were noted together with the rationale for such. At the end of the day the authorizing GP had to go through the patient lists generated by the CSS pharmacist and approve all the changes made. The Panel was concerned that medication changes were made by the CSS pharmacist and these were then authorized at the end of the day by the GP even though the meeting at the start of the day would give the CSS pharmacist clear direction of the GPs wishes. The Medication Summary Form stated that the form was a breakdown of the patient numbers on each of the strengths of branded/generic medication that the GP asked the CSS pharmacist to review. It appeared that the review was product led rather than patient led. However patients taking asthma medication would have to be moved to a CFC free medication due to the non availability of CFC containing medication.

The Panel was concerned that some examples of patient letters which had been provided appeared to indicate that it was anticipated that as a result of the CSS patients would be changed onto Trinity-Chiesi's product Clenil Modulite. Nonetheless the Panel considered, on the basis of the information before it, that there was no evidence to show that the CSS acted as a switch service whereby patients were simply switched from one product to another without clinical review. No breach of Clauses 18.1 and 18.4 was ruled. The Panel also considered that there was no breach of Clauses 2 and 9.1 and ruled accordingly.

Complaint received **11 March 2008**

Case completed **15 April 2008**