TEVA v TRINITY-CHIESI

Clinical support service

Teva complained about a Clinic Support Service (CSS) with particular reference to two CSS pharmacist forms dated 2 and 24 October 2007 respectively used by Trinity-Chiesi. These CSS pharmacist forms were the basis of Teva's concern; Teva submitted that they represented the CSS service as a whole.

Each form had been signed by a pharmacist, a member of the Trinity-Chiesi CSS team. The forms were headed 'For the attention of the pharmacist' and told the reader that having assisted the named GP practice with issues relating to prescribing, there was likely to be an increased use of Clenil Modulite (CFC-free beclometasone dipropionate BDP) in place of CFC BDP. The form was an advisory note to help pharmacists plan stock levels of the various products concerned. Each form advised of a 'Likely INCREASED use of' Clenil Modulite and in addition the form dated 24 October also advised of an increased use of CFC-free inhalers. The form dated 2 October advised of a 'Possibly REDUCED use of', 'Beclometasone, Beclazone, Becotide and Becloforte pmdi' whilst the form dated 24 October referred simply to 'Beclometasone CFC-containing pmdi's [sic]'. Teva's product Qvar was a CFC-free BDP inhaler for asthma.

Teva noted that there was nothing on the forms at issue to indicate what work had been carried out at the GP practice, whether the work was endorsed by the GP or whether the changes noted on the form had been agreed with the GP. The pharmacist could have simply written the form themselves to ensure that the listed products were switched to Clenil. Teva noted that the Code stated that 'sponsored healthcare professionals should not be involved in the promotion of specific products'. It also stated that 'registration status should not be used in the promotion of commercial products or services'. The forms started with the words 'Dear colleague' and described the sender as 'a fellow pharmacist' who had been 'assisting the above practice with certain issues relating to prescribing'. Teva concluded that the lack of customer endorsement of any agreed actions on the forms was clear evidence of a breach of the Code and of an assisted switch to Clenil Modulite. In addition the phrase 'as a fellow pharmacist' abused the position of the Trinity-Chiesi pharmacist and was likely to contravene professional guidance issued by the Royal Pharmaceutical Society of Great Britain (RPSGB).

The Code also stated that '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'.

It was not clear that therapeutic review had taken place ensuring the patient received optimal treatment following a clinical assessment taking into account their specific individual disease. Both of the CSS pharmacist forms stated that there would now be a 'possible reduced use of ' CFC BDP and a 'likely increased use of ' Clenil Modulite CFC free inhalers. This therefore stated the use of the Trinity-Chiesi product as the likely change to prescribing and indicated that the service as a whole was limited to the medicines of the sponsoring company only. This was therefore clear evidence of a breach.

In Teva's opinion, these two clear breaches were enough to also lead to subsequent further breaches, including a breach of Clause 2.

The Panel noted that Teva had made its complaint solely on the basis of the two forms at issue. The Panel noted Teva's concern that sponsored health professionals should not be involved in the promotion of specific products and that registration status should not be used in the promotion of commercial products or services. The pharmacists that formed Trinity-Chiesi's CSS team were not sponsored health professionals – they were employees of the company. The Panel considered that the forms at issue were not sufficiently clear about the role of the pharmacists employed by Trinity-Chiesi. Community pharmacists reading the form would not necessarily consider an employee of a pharmaceutical company – albeit that employee was a pharmacist – as a colleague. The Panel did not consider that the lack of customer endorsement on the forms at issue of any agreed actions provided clear evidence that Trinity-Chiesi's service was a switch to Clenil Modulite which would be a breach of the Code rather than a therapeutic review. On the very narrow basis of the complaint made, the Panel ruled no breach.

The Panel noted that the forms referred to by Teva were just one part of the overall service offering. Only two forms had been provided by Teva. The Panel considered that, on the basis of the two forms before it, there was no evidence to show that the service as a whole was limited to Trinity-Chiesi's products. The Panel did not consider that it had a complaint about the clinical support service as a whole. No breach was ruled.

The forms at issue did not demonstrate that an inducement to prescribe, supply administer, recommend, buy or sell any medicine has been

offered or given. Thus the Panel ruled no breach in that regard. Given the circumstances there was no breach of Clause 2.

Teva UK Limited complained about a Clinic Support Service (CSS) with particular reference to two CSS pharmacist forms (ref TRCSS20040235) dated 2 and 24 October 2007 respectively used by Trinity-Chiesi Pharmaceuticals Ltd. These CSS pharmacist forms were the basis of Teva's concern; Teva submitted that they represented the CSS service as a whole.

Each form had been signed by a pharmacist, a member of the Trinity-Chiesi CSS team. The forms were headed 'For the attention of the pharmacist' and told the reader that having assisted the named GP practice with issues relating to prescribing, there was likely to be an increased use of Clenil Modulite (CFC-free beclometasone dipropionate BDP) in place of CFC BDP products. The form was sent to the pharmacist as an advisory note to help with stocking the various products concerned.
The section of each of the forms headed 'Likely INCREASED use of' had 'Clenil Modulite' written in it and in addition the form dated 24 October also stated 'CFC-Free inhalers'. The forms also had a section headed 'Possibly REDUCED use of'. On the form dated 2 October this section was completed with 'Beclometasone Beclazone, Becotide and Becloforte pmdi'. On the form dated 24 October this section was completed with 'Beclometasone CFC-containing pmdi's [sic]'. Teva's product Qvar was a CFC-free BDP inhaler for asthma.

COMPLAINT

Teva noted that there was no customer signature or endorsement of the actions on either form and so no evidence as to whether the pharmacist had been working with GPs or had simply written the form themselves to ensure that the listed products were switched to Clenil. This was misleading to say the very least as it did not state what this work was and also did not indicate whether any changes had been agreed with the relevant GPs.

Furthermore, the forms did not appear to have a slot allocated to a customer signature. This significant omission had a number of implications and led Teva to the following two major conclusions related to the CSS service as a whole.

1 Clause 18.4 (vi) of the supplementary information to the Code stated that 'sponsored healthcare professionals should not be involved in the promotion of specific products'. It also stated that 'registration status should not be used in the promotion of commercial products or services'.

  This form started with the words 'Dear colleague' and described the sender as 'a fellow pharmacist', who had been 'assisting the above practice with certain issues relating to prescribing'. Given the lack of customer endorsement of any agreed actions on this form then Teva concluded that this form was clear evidence of a breach of the Code and evidence of an assisted switch to Clenil Modulite. In addition the phrase 'as a fellow pharmacist' abused the position of the Trinity-Chiesi pharmacist and in Teva's view was likely to contravene professional guidance issued by the Royal Pharmaceutical Society of Great Britain (RPSGB). In Teva's view, this was clear evidence of a breach of Clause 18.4.

2 The supplementary information to Clause 18.4 also stated that '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'.

  It was not clear that a therapeutic review had taken place ensuring the patient received optimal treatment following a clinical assessment taking into account their specific individual disease. Both of the CSS pharmacist forms stated that there would now be a 'possible reduced use of ' CFC BDP and a 'likely increased use of ' Clenil Modulite CFC free inhalers. This therefore stated the use of the Trinity-Chiesi product as the likely change to prescribing and indicated that the service as a whole was limited to the medicines of the sponsoring company only. This was therefore clear evidence of a breach of Clause 18.4. In Teva's opinion, these two clear breaches of the Code were enough to also lead to subsequent further breaches of Clauses 2, 9.1 and 18.1.

RESPONSE

Trinity-Chiesi explained that the form at issue was used by its clinical support team to inform the local community pharmacists of the outcomes of the CSS which had been carried out in their local surgery and which might directly affect them and the service they provided. The form helped to ensure that the appropriate medicine was available and consistent patient information was provided from all members of the primary healthcare team. All pharmacists were accountable for the quality and standards of the services they provided and for their individual professional practice and the forms formed part of the clinical governance used by the CSS pharmacists to maintain and improve the quality of their professional practice.

The forms were in effect letters advising the community pharmacist of the likely outcome of the CSS which had been carried out within the surgery as authorised by the necessary GP/GPs. This letter did not require a customer signature as no action was required by the community pharmacist, it was purely an advisory letter between two health professionals. The letter did not contain or imply any promotion of commercial products or services.

As the letter was from a pharmacist to a fellow pharmacist within community pharmacy the terms 'Colleague' and 'fellow pharmacist' were valid, aided effective communication and did not represent any breach of the Code. The use of the term 'fellow pharmacist' was a professional courtesy and clearly did not abuse any position. This form was introduced to ensure the pharmacists complied fully with the RPSGB Medicines, Ethics and Practice guidelines and Teva's suggestion of a contravention of these guidelines was unsubstantiated and not valid. Furthermore, as the letter referred to the CSS which had been duly authorised by the GP and completed within the surgery, the term 'assisting the above practice with certain issues relating to prescribing' was used to explain those outcomes of the CSS which would be seen by the community pharmacist.

Trinity-Chiesi submitted that its CSS service complied with the guidelines set out in the supplementary information to Clause 18.4:

> 'A therapeutic review is different to a switch service. A therapeutic review service which aims to ensure that patients receive optimal treatment following a clinical assessment is a legitimate activity for a pharmaceutical company to support and/or assist. The results of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medication 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 arrangements for 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. 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 form at issue in isolation communicated any changes of medicine made for patients by the prescriber and each change would have been duly documented that it was made on rational grounds and would have been duly authorised and signed by the prescriber. The clinical assessments made by the pharmacist during the provision of the service would include interactions, over/under ordering of medicines, duplicate therapies, compliance issues, dosages, strengths, licensed indications, quantities issued and inequivalence of quantities, clinical investigations - tests overdue or not recorded, side effects and strength optimisation. Any of the clinical outcomes which occurred as a result of these assessments, such as cessation of treatment or change of dose would be detailed on a medication query form and discussed directly with the authorising GP. Such outcomes would obviously not be detailed on the form at issue and Teva's assumption that this would be the case was incorrect.

Trinity-Chiesi noted that Teva's complaint was almost identical to inter-company correspondence dated 21 December 2007 save the additional statement 'What is not clear is whether any therapeutic review has taken place ensuring the patient receives optimal treatment following a clinical assessment, taking into account their specific individual disease…'.

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

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

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

From its detailed response above Trinity-Chiesi did not agree that the concerns raised by Teva were in breach of Clauses 2, 9.1, 18.1 or 18.4.

In addition to responding to the complaint, Trinity-Chiesi considered that in this case the correct complaint procedure had not been followed by Teva and that inter-company dialogue was not complete. Details were provided.

PANEL RULING

The Director decided that taking all circumstances into account that inter-company dialogue satisfied Paragraph 5.2 of the Constitution and Procedure and the complaint should proceed.

The Panel noted that Teva had made its complaint

solely on the basis of the two forms at issue. The Panel noted Teva's concern that sponsored health professionals should not be involved in the promotion of specific products and that registration status should not be used in the promotion of commercial products or services. The pharmacists that formed Trinity-Chiesi's CSS team were not sponsored health professionals – they were employees of the company. The Panel considered that the forms at issue were not sufficiently clear about the role of the pharmacists employed by Trinity-Chiesi. Community pharmacists reading the form would not necessarily consider an employee of a pharmaceutical company – albeit that employee was a pharmacist – as a colleague. The Panel did not consider that the lack of customer endorsement on the forms at issue of any agreed actions provided clear evidence that Trinity-Chiesi's service was a switch to Clenil Modulite which would be a breach of Clause 18.4 rather than a therapeutic review. On the very narrow basis of the complaint made, the Panel ruled no breach of Clause 18.4.

The Panel noted that the forms referred to by Teva were just one part of the overall service offering. Only two forms had been provided by Teva. The Panel considered that, on the basis of the two forms before it, there was no evidence to show that the service as a whole was limited to Trinity-Chiesi's products. As noted above the Panel did not consider that it had a complaint about the clinical support service as a whole. No breach of Clause 18.4 was ruled.

Bearing in mind its ruling of no breach of Clause 18.4, the Panel did not consider there was a breach of Clause 18.1. The forms at issue did not demonstrate that an inducement to prescribe, supply administer, recommend, buy or sell any medicine has been offered or given. Thus the Panel ruled no breach of Clause 18.1. Given the circumstances there was no breach of Clauses 2 and 9.1.

Complaint received **14 February 2008**

Case completed **22 April 2008**