PRIMARY CARE TRUST ASSISTANT DIRECTOR OF CLINICAL SERVICES v TRINITY-CHIESI

Primary Care Report – CFC-free inhalers

The assistant director of clinical services at a primary care trust (PCT) complained about special edition 3, December 2006, of Primary Care Report which dealt with CFC-free inhalers. At the bottom of the front cover it was stated that 'This edition of *Primary Care Report* is sponsored by Trinity-Chiesi Pharmaceuticals Ltd'.

The item comprised four pages. The front page was headed 'Becotide/Becloforte withdrawal forces treatment reviews' and referred to the transition to CFC-free beclometasone dipropionate (BDP). Trinity-Chiesi's BDP product, Clenil Modulite, was described as a CFC-free, dose equivalent alternative to Becotide/Becloforte.

The complainant stated that this document purported to be 'The first choice for primary care leaders' and appeared to be a series of articles regarding inhaled steroid prescribing. On reading the articles the complainant considered them to be one long advertisement for Clenil Modulite. It was extremely one sided and contained technical inaccuracies that further pushed the prescribing of this preparation.

The first article, on Becotide withdrawal, stated that Department of Health (DoH) policy was that 'CFCs will no longer be considered essential in products containing inhaled steroids in the UK once two alternative products containing beclometasone are available'. This was not referenced but was different to the advice that was being given from the local strategic health authority prescribing advisor who stated that there must be two preparations of equal potency available.

This was not the case currently and until this happened generic BDP would continue to be available. This was not mentioned in the article neither was it stated that when beclometasone (sic) was discontinued patients could be simply switched to the generic equivalent which was considerably cheaper then Clenil. The second article gave an example of a switch programme from Becotide to Clenil. The advertisement continued. The third article was a review of Clenil. The advertisement continued.

The complainant considered it unacceptable to dress up an advertisement for a medicine as a series of articles. The Primary Care Report stated that it was sponsored by Trinity-Chiesi; however this did not protect the reader from the bias that was inherent in the articles which the complainant considered were misleading and incorrect.

The Panel noted that the Primary Care Report had been sponsored by Trinity-Chiesi and approved by the company as a piece of promotional material.

The Panel considered the immediate visual impression of the front page. Given the recent changing nature of the Primary Care Report, the Panel considered that it would be difficult to substantiate the statement beneath the title Primary Care Report that it was 'The first choice for primary care leaders'. The left hand column described Clenil Modulite as a CFC-free dose equivalent alternative to Becotide/Becloforte. As well as including the declaration of sponsorship, the front page stated that prescribing information was available on page 4. The main article on page 1 gave no details as to the status of the author. The article on page 2 was written by a freelance journalist. Although the Primary Care Report was dated and had an edition number, suggesting one in a series of publications, the Panel considered that on balance most readers would view the material as promotional. The document did not look like a medical journal or any other official publication. The Panel did not consider that the promotional nature of the material had been disguised. No breach of the Code was ruled.

The Panel noted the 1999 DoH Transition Strategy stated that the use of CFCs in a medicine containing beclometasone would no longer be considered essential once two alternative CFC-free MDI products containing the same medicine and meeting the needs of all patient groups were available from two different producers. In addition the transition strategy stated that CFCs in inhaled steroids would no longer be considered essential once two alternative products containing beclometasone and at least one CFC-free MDI product for each of budesonide and flucticasone were available in an adequate range of doses. This was included in the Primary Care Report article.

The Panel noted that the statement about the DoH advice was not referenced but the Code did not require it to be so. The Code required that all claims etc were capable of substantiation. The Panel noted there appeared to be a discrepancy between the DoH advice and the advice given by the complainant's strategic health authority. The Primary Care Report was not misleading in this regard and no breach of the Code was ruled.

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COMPLAINT

The complainant stated that this document purported to be 'The first choice for primary care leaders' and appeared to be a series of articles regarding inhaled steroid prescribing. On reading the articles the complainant considered them to be one long advertisement for Clenil Modulite. It was extremely one sided and contained technical inaccuracies that further pushed the prescribing of this preparation.

The first article, on Becotide withdrawal, stated that Department of Health (DoH) policy was that 'CFCs will no longer be considered essential in products containing inhaled steroids in the UK once two alternative products containing beclometasone are available'. This was not referenced but was different to the advice that was being given from the local strategic health authority prescribing advisor who stated that there must be two preparations of equal potency available.

This was not the case currently and until this happened generic BDP would continue to be available. This was not mentioned in the article neither was it stated that when beclometasone (sic) was discontinued patients could be simply switched to the generic equivalent which was considerably cheaper then Clenil. The second article gave an example of a switch programme from Becotide to Clenil. The advertisement continued. The third article was a review of Clenil. The advertisement continued.

The complainant did not consider that it was acceptable to dress up an advertisement for a medicine as a series of articles. The Primary Care Report stated that it was sponsored by Trinity-Chiesi; however this did not protect the reader from the bias that was inherent in the articles. The complainant considered that these articles were misleading and incorrect.

When writing to Trinity-Chiesi, the Authority asked it to respond in relation to Clauses 7.2, 9.1 and 10.1 of the Code.

RESPONSE

Trinity-Chiesi stated that Primary Care Report was published by a long-established publisher of medical journals and titles. Primary Care Report began as a weekly publication in 2002 and targeted 12,500 primary care decision-makers in England. However, in response to the changing NHS environment and the needs and dynamics of PCTs, the publishers stopped regular publication of Primary Care Report in 2005 and re-launched the title as a sponsored supplement in early 2006. The sponsored supplement had always carried the same statement 'first choice for primary care leaders' since it was launched. This publication operated as a sole sponsored journal with key opinion leader interviews and articles and a back page for the sponsor's product or corporate advertisement.

Trinity-Chiesi sponsored the December 2006 edition of Primary Care Report, which was sent to 28,000 GPs as a supplement to the BMJ (which also evaluated the copy to ensure it did not infringe its publishing ethos), sent to approximately 11,200 primary care organisation contacts across England (including public health, finance, medicines management and commissioning representatives) and distributed via the Trinity-Chiesi sales team (17,500 printed).

Whilst Trinity-Chiesi was sorry that the complainant appeared to have been disappointed with the content the company believed it was clearly a promotional piece. It was a stand alone booklet which stated on the front cover that it had been sponsored by a pharmaceutical company; this statement was made prominent by a highlighted band and in addition the text was larger than the body copy. The document also contained a number of other indications that it was a promotional item eg it contained prescribing information and clearly stated where this could found, and the most prominent mention of the product name carried a large inverted black triangle. This supplement was not one sided and focused on the two alterative CFC-free BDP pressurised inhalers that were currently available. Trinity-Chiesi did not believe it could be considered to be disguised promotion (Clause 10.1).

Trinity-Chiesi noted that the DoH document 'UK Transition Strategy for CFC-based MDIs [metered dose inhalers] – September 1999' stated that CFCs would no longer be considered essential in products containing inhaled steroids in the UK once two or more alternative products containing beclometasone and at least one CFC-free MDI for each of budesonide and fluticasone were available in an adequate range of doses for all patient groups. There were no published updates to this document and Trinity-Chiesi believed that it represented current policy. The Code did not require every item of information to be referenced although all statements made must be capable of substantiation as the advice given in the article at issue thus was. Clearly there appeared to be a discrepancy between the UK Transition Strategy document and the advice given (or interpretations of advice given) by the complainant's strategic health authority. Trinity-Chiesi did not believe that the advice was in breach of Clause 7.2 of the Code; it was an accurate and unambiguous reflection of current DoH policy.

The Primary Care Report aimed to highlight the withdrawal of two major CFC-containing inhaled steroids, GlaxoSmithKline's Becotide and Becloforte, within the context of the DoH policy on CFC-free MDIs and the availability of Clenil Modulite. It discussed the

pragmatic solutions and processes that the quoted health professionals had identified as being appropriate to implement once they had decided that their patients would need to change to a CFC-free inhaler. The Primary Care Report did not state that patients on Becotide or Becloforte **would** have to change to a CFC-free inhaler, only that in view of the eventual need to change all patients to CFC-free devices, and the recent availability of a CFC-free BDP which enabled a direct switch, it might be appropriate to change patients directly to Clenil Modulite. Trinity-Chiesi believed that this argument was not misleading and had been presented in a balanced and accurate manner. Trinity-Chiesi did not believe that there was a breach of Clause 7.2.

Trinity-Chiesi regretted causing offence to any customer; it had not received any other complaints or negative comments about the item which was reviewed and approved through the company's Code compliance process. Trinity-Chiesi believed that the issue of CFCs was particularly important given current environmental concerns and that highlighting the effects of the eventual withdrawal of CFC-containing inhalers on those working in primary care was a responsible action, as well as being in line with its promotional strategy. In producing this item Trinity-Chiesi believed that it had upheld the high standards required.

PANEL RULING

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its content, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.

The Panel noted that the Primary Care Report had been sponsored by Trinity-Chiesi and used by its representatives. No information had been given about the role of Trinity-Chiesi in the production of the Primary Care Report. The company had approved the item as a piece of promotional material.

The Panel considered the immediate visual impression of the front page. Given the changing nature of the Primary Care Report, the Panel considered that it would be difficult to substantiate the statement that it was 'The first choice for primary care leaders'. The left hand column described Clenil Modulite as a CFC-free dose equivalent alternative to Becotide/Becloforte. As well as including the declaration of sponsorship, the front page stated that prescribing information was available on page 4. The main article on page 1 gave no details as to the status of the author. The article on page 2 was written by a freelance journalist. Although the Primary Care Report was dated and had an edition number, suggesting one in a series of publications, the Panel considered that on balance most readers would view the material as promotional. The document did not look like a medical journal or any other official publication. The Panel did not consider that the promotional nature of the material had been disguised. No breach of Clause 10.1 was ruled.

The Panel noted the 1999 DoH Transition Strategy stated that the use of CFCs in a medicine containing beclometasone would no longer be considered essential once two alternative CFC-free MDI products containing the same medicine and meeting the needs of all patient groups were available from two different producers. In addition the transition strategy stated that CFCs in inhaled steroids would no longer be considered essential once two alternative products containing beclometasone and at least one CFC-free MDI product for each of budesonide and fluticasone were available in an adequate range of doses. This was included in the Primary Care Report article.

The Panel noted that the statement about the DoH advice was not referenced but under the Code it was not required to be so. The Code required that all claims etc were capable of substantiation. The Panel noted there appeared to be a discrepancy between the DoH advice and the advice given by the complainant's strategic health authority. The Primary Care Report was not misleading in this regard and no breach of Clause 7.2 was ruled.

The Panel noted its no breach rulings above and thus decided there was no breach of Clause 9.1.

Complaint received 19 December 2006

Case completed 20 February 2007