

PRIMARY CARE TRUST ASSISTANT DIRECTOR OF MEDICINES MANAGEMENT v TAKEDA

Amias mailing

The assistant director, medicines management, at a primary care trust (PCT) complained about a mailing produced by Takeda entitled 'Reducing Hypertension Spend in ... PCT' which discussed the potential local cost savings if Amias (candesartan) was prescribed.

The mailing had been sent without any cover note or identification to each GP in the PCT. The information had been used and presented in a misleading way. GPs had contacted the complainant to ask if this had been officially endorsed by the PCT as the presentation appeared to make it so.

The Panel noted that the leaflet, 'Reducing Hypertension Management Spend in ... PCT' was subtitled 'A review of the current financial status of ... PCT and a strategy to reduce practice spend in the treatment of hypertension'. The inside front cover discussed a financial review and asked what steps could be taken to: assist in the achievement of this year's financial targets; help patients with hypertension and reduce prescribing costs. The third page was headed 'How To Reduce Angiotension Reception Blocker (ARB) Spend in ... PCT by up to £106,000/1,000 patients treated for a year', and discussed the cost of prescribing Amias compared with losartan and valsartan. There was no indication that it had been produced by Takeda or that it was promotional material for Amias. The inclusion of prescribing information on the back cover did not suffice in this regard.

The Panel considered that the source of the leaflet was not sufficiently clear. Whilst the leaflet did not use the logo of the PCT it nonetheless referred to the organisation ten times. Conversely Takeda's name appeared only twice, in small print on the back page in the prescribing information. According to the complainant a number of GPs had queried whether the leaflet had been endorsed by the PCT as its presentation appeared to make it so. The Panel considered that the failure to indicate at the outset that this was company produced material gave the impression that the leaflet was something other than promotional material and was misleading and disguised in this regard. Breaches of the Code were ruled.

The assistant director, medicines management, at a primary care trust (PCT) complained about a mailing (ref TA070111) produced by Takeda UK Ltd. The mailing was entitled 'Reducing Hypertension Spend in ... PCT' and discussed the potential local cost savings if Amias (candesartan) was prescribed.

COMPLAINT

The complainant stated that the mailing had been sent without any cover note or identification to each GP in the PCT. Whilst the information had been accessed from public documents, it had been used and presented in a misleading way. A number of GPs had contacted the complainant to ask if this had been officially endorsed by the PCT as the presentation appeared to make it so, especially as there was no company logo or covering letter to identify the author/source.

The complainant was uncertain as to whether any code had been breached but the PCT found this method of promotion unacceptable.

When writing to Takeda, the Authority asked it to respond in relation to Clauses 7.2 and 10.1 of the Code.

RESPONSE

Takeda stated that it was obviously concerned that a health professional considered that the piece was misleading and it took this allegation very seriously. It was absolutely not Takeda's intention for any of its materials to be misleading and it had thoroughly reviewed the mailing with particular focus, as requested, on Clauses 7.2 and 10.1.

Takeda noted that the mailing was an A5 size folded leaflet consisting of four pages of information. It was sent on its own in a plain envelope to GPs in the PCT.

Takeda explained that following the reorganisation of the company in 2004, it had moved away from traditional, highly product branded promotional materials to a more formal, clinical or corporate style. This style and corporate branding had been consistent since 2004 and had been used for the majority of Takeda materials as well as its corporate branded stationary and website. Examples of this were provided. The mailing at issue did not, and was not designed to mimic an NHS document/template and did not use either NHS or the PCT branding or logos anywhere. The PCT had a clear and consistent branding which was used on its publications and website – copies were provided. The mailing did not resemble the PCT material in any way, including the publicly available annual report from which the financial information was sourced. Takeda's regional account director who covered the PCT area had produced the mailing; it was a locally focused piece, produced specifically for local GPs. The reference to the PCT was used to define a particular geography and the local

healthcare economy applicable to the recipients of the mailer. This local information was more relevant and applicable than, for example, national figures. There was nothing in the mailing that suggested the information was endorsed by, or produced by the PCT. It just stated the current financial situation in the local healthcare economy that was relevant to the audience. The information included on page 2 was publicly available on the PCT website. This financial information was provided to set the scene and reinforce the environment that the local GPs currently faced.

Takeda noted that page 3 (which formed the bulk of the mailer) provided promotional information about Amias. It reinforced both the clinical and financial benefits of using candesartan compared with the other two leading angiotension receptor blockers within the PCT region.

The final page was taken up by the Amias prescribing information. This was clearly a promotional piece and there had been no attempt to disguise that fact. Page 4 also included the required contact details for adverse event reporting and for obtaining further information on Amias.

The inclusion of prescribing information *per se*, demonstrated that the piece was an intentionally promotional piece for a medicine and not an official NHS document which would not include such information.

Takeda noted that the piece met all the necessary requirements of a promotional piece. It was certified prior to use and included the unique job code number, date of preparation, prescribing information and prominent information relating to adverse event reporting. The piece generally included the non-proprietary name of the product in preference to brand name although the brand name did appear in the main body of the piece as well as the prescribing information. There was no specific requirement in the Code for a piece to include a company logo.

Based on the above, Takeda did not believe that the piece was intentionally misleading, nor was it disguised promotion and did not believe that it was in breach of Clauses 7.2 and 10.1. However, to prevent any further misunderstanding, Takeda would ensure

that all future promotional pieces included a clear product or corporate logo.

PANEL RULING

The Panel noted that the leaflet, 'Reducing Hypertension Management Spend in ... PCT' was subtitled 'A review of the current financial status of ... PCT and a strategy to reduce practice spend in the treatment of hypertension'. The inside front cover discussed a local operating and financial review and asked what steps could be taken to: assist in the achievement of this year's financial targets; help patients with hypertension and reduce prescribing costs. The third page was headed 'How To Reduce Angiotension Reception Blocker (ARB) Spend in ... PCT by up to £106,000/1,000 patients treated for a year', and discussed the cost of prescribing Amias compared with losartan and valsartan. Prescribing information appeared on page 4 (the back cover). There was no indication on the front page or within that this leaflet had been produced by Takeda or that it was promotional material for Amias. The inclusion of prescribing information did not suffice in this regard.

The Panel considered that the source of the leaflet was not sufficiently clear. Whilst the leaflet did not use the logo of the PCT it nonetheless referred to the organisation ten times throughout the leaflet. Conversely Takeda's name appeared only twice, in small print on the back page in the prescribing information. Similarly, apart from the prescribing information 'Amias' appeared only twice, in brackets in the main part of the leaflet; 'candesartan' was used seven times. According to the complainant a number of GPs had queried whether the leaflet had been endorsed by the PCT as its presentation appeared to make it so. The Panel considered that the failure to indicate at the outset that this was company produced material gave the impression that the leaflet was something other than promotional material and was misleading and disguised in this regard. Breaches of Clauses 7.2 and 10.1 were ruled.

Complaint received	19 March 2007
Case completed	15 May 2007