

GENERAL PRACTITIONERS v PROCTER & GAMBLE

'Dear Doctor' letter about mesalazine

Two general practitioners complained separately about a letter received from a university hospital professor, which referred to the prescribing of mesalazine preparations. The letter had been sponsored by an educational grant from Procter & Gamble. Procter & Gamble supplied Asacol (mesalazine modified release).

In both cases the complainants alleged that the letter was disguised promotion. In Case AUTH/1898/10/06 the complainant submitted that the disguise had been effected by using the professor to write the letter on his departmental letter heading (whether ghost written/edited or not), and by not mentioning the product name, when recipients would be fully aware of what was intended. The complainant further noted that letter appeared to have been sent to all UK GPs but the professor worked in a centre of excellence in another area; the complainant was very unlikely to refer patients to him. The complainant in Case AUTH/1900/10/06 submitted that the professor had completely denied responsibility for the use of the letter in a nationwide campaign.

The Panel noted that the letter was about the general issue of prescribing oral mesalazine. Recipients were reminded that mesalazine preparations differed in their release characteristics and as such should not be considered interchangeable. Once a patient was maintained on one particular brand of mesalazine it was important that they remained on that brand and were not given generic prescriptions which would mean that they might receive a different brand. The Panel noted that the letter did not mention any particular brand of oral mesalazine either by name or by implication. In that regard, given the general nature of the letter, the Panel did not consider that it promoted Asacol. The letter thus did not require prescribing information for Asacol. No breach of the Code was ruled. The letter also, therefore, did not constitute disguised promotion for Asacol. No breach of the Code was ruled.

With regard to the distribution of the letter the Panel noted that the professor had relied upon the supplier assigned to carry out the mailing. The Panel considered that if this supplier had been appointed by Procter & Gamble the company should have briefed the supplier such that there was no misunderstanding as to whom the mailing was to be sent. It was not clear who generated the final mailing list and on what basis but it appeared that the mailing had gone to more people than the professor had originally envisaged. In that regard the Panel considered that Procter & Gamble might not have managed the project with enough care to ensure that high standards were maintained. In addition the Panel noted that Procter & Gamble had paid for the mailing costs and thus the statement that the letter had been sponsored by an educational grant was misleading. In the Panel's view it was beholden upon companies not only to declare their sponsorship of material but also to be very clear about the nature of the sponsorship. Overall high standards had not been maintained. A breach of the Code was ruled.

Two general practitioners (Case AUTH/1898/10/06 and Case AUTH/1900/10/06), complained separately about a letter received from a university hospital professor, which referred to the prescribing of mesalazine preparations. The letter was dated 2 October 2006 but at the bottom of the second (and final) page it was stated that its date of preparation was 1 September 2006 and the reference AS 7285 was given. It was stated on both pages that the letter had been sponsored by an educational grant from Procter & Gamble Pharmaceuticals.

The complaints were taken up with Procter & Gamble Pharmaceuticals UK Limited, which supplied Asacol (mesalazine modified release).

Case AUTH/1898/10/06

COMPLAINT

The complainant alleged that the letter he had received from the professor was in breach of the Code as it was disguised promotion for Asacol. The disguise had been effected by the use of the professor to write it on his departmental letter heading (whether ghost written/edited or not), and by the specific device of not mentioning the product name, when recipients would be fully aware of what was intended. This dovetailed into existing overt advertising on this theme by Procter & Gamble.

The letter came to the complainant on the professor's own departmental headed notepaper as his own opinion, as it might well be. The small print at the bottom of the page indicated that it was 'Supported by an educational grant from Procter & Gamble Pharmaceuticals'. The final line 'Date of preparation 1 September 2006. AS7285' suggested AS for Asacol and 7285 being a large number had probably originated from Procter & Gamble rather than the professor. The professor had not declared the extent of this 'support' or indeed the extent to which Procter & Gamble might fund his other activities.

The letter appeared to be one of a mass mailing, presumably to all UK GPs, which was a not inconsiderable expense. The complainant did not object to the sentiment expressed, which he had long adopted, in fact, in favour of this product. This information was therefore not relevant to him. The professor might work in a centre of excellence, but it was in a different country even from the one in which the complainant worked. He had no professional relation with him and his primary care organisation would not fund NHS referrals to him except on a special and case-by-case basis.

To the complainant this was clearly a promotional mailing by Procter & Gamble to all GPs and should have been presented as such, with a quotation from the professor placed within the body of the text if appropriate.

Openness of intent and declaration of financial support was now an important part of relations between doctors and the pharmaceutical industry. The complainant would be glad if the Authority could consider this issue and communicate its findings to all parties.

Case AUTH/1900/10/06

COMPLAINT

The complainant alleged that the letter in question was disguised promotion in breach of the Code.

He had discussed the matter with the professor who completely denied responsibility for the use of this letter in a nationwide campaign.

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When writing to Procter & Gamble about the complaints, the Authority asked it to respond in relation to Clauses 4.1 (Case AUTH/1898/10/06 only), 9.1 and 10.1 of the Code.

Cases AUTH/1898/10/06 and AUTH/1900/10/06

RESPONSE

Procter & Gamble stated that the professor had undertaken a similar mailing to the one in question in 2002 with no involvement from the company. The message of the original letter was still important and Procter & Gamble offered to support a repeat mailing. Neither Procter & Gamble nor the professor intended promoting any particular brand of oral mesalazine in this letter. Procter & Gamble did not consider that the letter promoted any brand of oral mesalazine and it was sorry if the letter had given some recipients that impression.

As the letter only referred to the class of medicine, mesalazine, and did not mention any particular brand, it could not be considered a promotional piece. AS7285 was a unique and internal reference number issued by Procter & Gamble which was assigned to an item when it was reviewed by its copy review team. As the mailing of this item was sponsored by Procter & Gamble it was reviewed to ensure it was factually correct and that the statement of sponsorship was legible. This was not a promotional piece for Asacol and therefore prescribing information was not necessary. Procter & Gamble denied a breach of Clause 4.1.

In Procter & Gamble's view, the letter maintained the high standard expected for communication within the medical community.

The branded prescribing of oral mesalazines was recommended by most prescribing guides. Despite this, in 2006 nearly 40% of oral mesalazine prescriptions nationally were still being written generically. Based on this Procter & Gamble considered that the message and the format of the letter were both relevant and tasteful and therefore not a breach of Clause 9.1.

The 'Dear Doctor' letter was a mailing from the

professor and as such the views expressed therein belonged to him. The educational grant provided by Procter & Gamble was used to cover the postage costs and, as required by Clause 9.10, this sponsorship was declared on this letter. The letter did not refer to any particular brand of oral mesalazine.

Procter & Gamble considered that this letter could not be seen as disguised promotion and therefore there was no breach of Clause 10.1.

In response to a request for more information Procter & Gamble reiterated that the letter in question was initially written and mailed by the professor in 2002. The company enquired as to whether the professor would appreciate financial support in its re-printing and distribution by a third party. Procter & Gamble paid for these costs. The professor advocated re-sending the letter as he was committed to emphasising the importance of brand prescribing for continuity of care in inflammatory bowel disease. The importance of this message had already been highlighted in MIMS and the BNF and because of its relevance country wide, the letter was sent to health professionals throughout the UK. The list of recipients was decided by the professor. The letter was updated with information provided by Procter & Gamble to include the most recent statistics on branded prescribing. The professor was the author and final signatory of the letter. He had editorial control throughout.

The letter was not intended to promote a particular brand but to raise awareness of the importance of consistency of care in inflammatory bowel disease. Procter & Gamble therefore considered that the letter could not be seen as disguised promotion as the content was purely medical information.

In response to a further request for more information Procter & Gamble again stated that it did not consider that the letter at issue promoted Asacol. It did not mention any particular brand of oral mesalazine, therefore prescribing information was not necessary. Procter & Gamble regretted that the complainant was confused by the AS7285 reference, which was an internal certification reference number.

The letter had to be certified because Procter & Gamble had provided an educational grant to cover the mailing costs. As confirmed by the professor, acknowledgement of the source of funding for postage (not from the NHS) was simply to make this transparent rather than appear to be promotional. From discussions between the complainant and the professor it appeared that the nature and extent of the educational grant was initially not clear to the complainant, and had given him reason to complain. Clarification subsequently provided by the professor to the complainant had proven to be satisfactory to both parties.

Procter & Gamble had taken these insights very seriously and would be more specific on disclosing the extent of funding of an educational grant whenever future materials were developed.

In conclusion Procter & Gamble did not believe that the letter was in breach of Clause 4.1.

Procter & Gamble noted that it had previously argued

that the letter maintained the high standard expected for communication within the medical community:

- The issue regarding interchanging one oral mesalazine with another without proven equivalence in bioavailability was discussed widely by physicians caring for patients with inflammatory bowel disease. Both MIMS and the BNF noted that enteric coated mesalazine preparations should not be considered interchangeable.
- Often patients were inadvertently switched from a branded prescription to a generic one without their knowledge which could potentially increase the risk of relapse in stable patients. The letter therefore was intended to make physicians appreciate this risk.

Procter & Gamble thus considered that the content and format of the letter was both relevant and tasteful and therefore not in breach of Clause 9.1.

Procter & Gamble stated that the process by which the letter at issue was produced was:

- In August 2006, the professor initiated discussions with Procter & Gamble about the nature of prescribing mesalazine and the non-equivalence in bioavailability of available products.
- Procter & Gamble offered to fund the mailing of a letter on this topic to doctors.
- The educational grant was not directed to the professor himself.
- The professor had complete editorial control over the content of the letter and as such the views expressed in the letter were his.
- The professor's hospital had a very wide referral base given its responsibility as a tertiary referral centre which spread out across the UK. The professor acknowledged that the hospital did not have full details of the names and addresses of prescribing physicians across the country; therefore he relied upon the supplier assigned to carry out the mailing. Regrettably the communication on mailing coverage between the professor and the supplier (in which Procter & Gamble was not involved) was not ideal and did not allow each party to have a full appreciation of each other's interpretation of the reach of the hospital's wide referral base. This might have resulted in some 'overshoot of the mark'. As soon as this was realised, further mailing was stopped.

In conclusion, Procter & Gamble did not consider that

the letter was disguised promotion and therefore there was no breach of Clause 10.1.

PANEL RULING

The Panel noted that the letter was about the general issue of prescribing oral mesalazine. Recipients were reminded that mesalazine preparations differed in their release characteristics and as such should not be considered interchangeable. Once a patient was maintained on one particular brand of mesalazine it was important that they remained on that brand and were not given generic prescriptions which would mean that they might receive a different brand. The Panel noted that the letter did not mention any particular brand of oral mesalazine either by name or by implication. In that regard, given the general nature of the letter, the Panel did not consider that it promoted Asacol. The letter thus did not require prescribing information for Asacol. No breach of Clause 4.1 was ruled (Case AUTH/1898/10/06 only). The letter also, therefore, did not constitute disguised promotion for Asacol. No breach of Clause 10.1 was ruled.

With regard to the distribution of the letter the Panel noted that the professor had relied upon the supplier assigned to carry out the mailing. The Panel considered that if this supplier had been appointed by Procter & Gamble the company should have briefed the supplier such that there was no misunderstanding as to whom the mailing was to be sent. It was not clear who generated the final mailing list and on what basis but it appeared that the mailing had gone to more people than the professor had originally envisaged. In that regard the Panel considered that Procter & Gamble might not have managed the project with enough care to ensure that high standards were maintained. In addition the Panel noted that Procter & Gamble had paid for the mailing costs. In that regard the statement that the letter had been sponsored by an educational grant was misleading. In the Panel's view it was beholden upon companies not only to declare their sponsorship of material but also to be very clear about the nature of the sponsorship. Overall high standards had not been maintained. A breach of Clause 9.1 was ruled.

Complaints received

Case AUTH/1898/10/06	10 October 2006
Case AUTH/1900/10/06	12 October 2006
Cases completed	10 January 2007