

GENERAL PRACTITIONER v RECORDATI

Conduct of representative

A general practitioner complained about a letter received from a Recordati medical representative. The letter, which was not on company headed notepaper, asked the addressee if it was possible to have a brief appointment. The representative continued by stating that she was selling a dihydropyridine calcium channel blocker which was an inexpensive, long-acting treatment for hypertension. The letter also included information about the draft NICE/British Hypertension Society (BHS) Guidelines and stated that the changes made to these guidelines were prompted, at least in part, by the outcome of the Anglo Scandinavian Cardiac Outcomes Trial which showed benefits for the use of a dihydropyridine calcium antagonist. The representative stated that she would not try to sell her drug as a 'miracle cure' but asked that the reader might consider it second line in patients who had failed on first line therapy; she further stated that she was modestly hopeful that the reader would be surprised at how inexpensive and effective her medicine was. The draft guidelines from NICE/BHS were sent with the letter together with a proforma for the recipient to indicate whether they wanted to see the representative. A stamped addressed envelope was also enclosed for the doctor's reply.

The Panel noted that the principal role of a representative was to promote medicines. By discussing the efficacy of the dihydropyridine calcium channel blocker, and stating that it was inexpensive, the representative had made claims for the product. The letter was clearly written with the intention of seeking to promote the prescription, supply, sale or administration of Zanicidip (lercandipine).

The Panel considered that the representative's actions were totally unacceptable; there appeared to be a serious lack of understanding of the requirements of the Code. The representative had, in effect, created her own promotional material for Zanicidip but had not had it certified prior to use in accordance with the Code. The letter did not include prescribing information. A breach of the Code was ruled.

The Panel considered that the representative had failed to maintain a high standard of ethical conduct; neither had she complied with all the relevant clauses of the Code. A breach of the Code was ruled.

The Panel noted that although the letter was not on company headed notepaper, from the first two sentences it was clear that it had been written by a representative who was seeking an appointment to promote a dihydropyridine calcium channel blocker. In that regard the Panel did not consider that the letter was disguised promotion. No breach of the Code was ruled.

A general practitioner complained about a letter he had received from a medical representative with Recordati Pharmaceuticals Ltd. In the letter, which was not on company headed notepaper, the representative asked the addressee if it was possible to have a brief appointment. The representative continued by stating that she was selling a dihydropyridine calcium channel blocker which was

an inexpensive, long-acting treatment for hypertension. The letter also included information about the draft NICE/British Hypertension Society (BHS) Guidelines and stated that the changes made to these guidelines were prompted, at least in part, by the outcome of the Anglo Scandinavian Cardiac Outcomes Trial (ASCOT) which showed benefits for the use of a dihydropyridine calcium antagonist. The representative stated that she would not try to sell her drug as a 'miracle cure' but asked that the reader might consider it second line in patients who had failed on first line therapy; she further stated that she was modestly hopeful that the reader would be surprised at how inexpensive and effective her medicine was. The draft guidelines from NICE/BHS were sent with the letter together with a proforma for the recipient to indicate whether they wanted to see the representative. A stamped addressed envelope was also enclosed for the doctor's reply.

Recordati marketed Zanicidip (lercandipine) a dihydropyridine calcium channel blocker.

COMPLAINT

The complainant considered that the letter was in breach of the Code; he was concerned that it was not on company headed notepaper.

When writing to Recordati, the Authority asked it to respond in relation to Clauses 4.1, 10.1 and 15.2 of the Code.

RESPONSE

Recordati explained that its representative had written to a number of GPs in her area as part of her efforts to secure appointments in order to discuss its medicine. The letter was not written directly to advocate the use of a particular medicine but rather to engage the recipient's attention sufficiently to grant the representative an appointment. This purpose was clearly stated in the opening line. The letter continued by explaining why the representative considered a meeting would be useful without promoting the use of any identifiable medicine. The letter did not mention Zanicidip either by brand name or generic name and made clear that its intention was to ask for an appointment. Recordati therefore considered that the letter was not promotion as defined in Clause 1.2 and therefore was not in breach of Clause 4.1 of the Code. Further the letter did not purport to be a personal communication and its purpose was not disguised – although the letter was not on company headed paper, its opening lines, together with the inclusion of an email address and business card made clear that this was a business letter from Recordati. For both these reasons Recordati therefore did not consider that the letter was disguised promotion and denied a breach of Clause 10.1.

Recordati considered that neither the reason for writing the letter (responding to difficulties in obtaining appointments) nor its purpose (to seek appointments) was unethical. Although the third paragraph (beginning 'I have been very frustrated ...') could have been somewhat less blunt the company did not consider it was unethical.

Recordati submitted that a decision as to whether the representative had complied with all relevant requirements of the Code hinged on whether the letter was deemed to promote a medicine or was simply an attempt to secure an appointment. Recordati believed that the latter was the case and thus did not consider that the representative's conduct was in breach of the Code.

Recordati stated that all of its representatives had been trained in the spirit and letter of the Code. In addition the company had a number of procedures in place to minimize the risk of unintended breaches of the Code. These procedures were periodically reinforced with individual members of staff and across the company as a whole.

PANEL RULING

The Panel noted that it was not a foregone conclusion under the Code that only materials which mentioned a product by brand name or generic name were promotional. Materials which did not refer to a product by name could also be considered promotional. Each case would have to be considered on its own merits. The principal role of a

representative was to promote medicines. By discussing the efficacy of the dihydropyridine calcium channel blocker, and stating that it was inexpensive, the representative had made claims for the product. The letter was clearly written with the intention of seeking to promote the prescription, supply, sale or administration of Zanicip.

The Panel considered that the representative's actions were totally unacceptable; there appeared to be a serious lack of understanding of the requirements of the Code. The representative had, in effect, created her own promotional material for Zanicip but had not had it certified prior to use in accordance with Clause 14 of the Code. The letter did not include prescribing information. A breach of Clause 4.1 was ruled.

The Panel considered that the representative had failed to maintain a high standard of ethical conduct; neither had she complied with all the relevant clauses of the Code. A breach of Clause 15.2 was ruled.

The Panel noted that although the letter was not on company headed notepaper, from the first two sentences it was clear that it had been written by a representative who was seeking an appointment to promote a dihydropyridine calcium channel blocker. In that regard the Panel did not consider that the letter was disguised promotion. No breach of Clause 10.1 was ruled.

Complaint received	5 May 2006
Case completed	12 June 2006