

# MERCK SHARP & DOHME v GLAXOSMITHKLINE

## Provision of textbook to general practitioners

Merck Sharp & Dohme complained about a letter sent to general practitioners by a representative of Edinburgh Pharmaceuticals which was part of GlaxoSmithKline; the letter was on GlaxoSmithKline headed paper.

Merck Sharp & Dohme noted that the letter offered a free copy of the Oxford Handbook of General Practice and included a reply paid slip/envelope. The letter stated 'If you would like a copy delivered to you, please complete and return the slip below in the freepost envelope (no stamp required)'. It also stated that there was no obligation to grant the representative an interview at the time of delivery. The Oxford Handbook of General Practice had a recommended retail price far in excess of £6 plus VAT.

The letter was written by a medical representative and the activities and actions of all medical representatives were considered to be promotional under the terms of the Code. Merck Sharp & Dohme believed that the method by which this item was distributed at the very least allowed the possibility that its delivery could be linked with a promotional opportunity.

The Panel noted that representatives were inextricably linked to the provision and distribution of the textbooks. The representatives chose which doctors would be offered the books, signed the letters offering the books and then offered to deliver the books. The principal role of a representative was to call on doctors in relation to the promotion of medicines. In that regard the Panel considered that the way in which the textbooks had been provided did not meet the requirements for the provision of medical or educational goods or services and thus a breach of the Code was ruled.

Merck Sharp & Dohme Limited complained about a letter (ref LOM/STA/03/5748) sent to general practitioners by a representative of Edinburgh Pharmaceuticals. Edinburgh Pharmaceuticals was part of GlaxoSmithKline UK Limited and the letter was on GlaxoSmithKline headed paper.

### COMPLAINT

Merck Sharp & Dohme noted that the letter offered a free copy of the Oxford Handbook of General Practice and included a reply paid slip/envelope. The letter stated 'If you would like a copy delivered to you, please complete and return the slip below in the freepost envelope (no stamp required)'. It also stated that there was no obligation to grant the representative an interview at the time of delivery.

The Oxford Handbook of General Practice had a recommended retail price far in excess of £6 plus VAT. Whilst Merck Sharp & Dohme acknowledged that the supplementary information to Clause 18.2 of the 2006 Code stated 'Certain independently produced medical/educational publications such as text books have been held to be acceptable under Clause 18.2 ...', it did not believe that initiatives such as the GlaxoSmithKline Book Club could claim exemption

under this clause. Rather, Merck Sharp & Dohme believed that this book was a promotional aid and as such was in breach of Clause 18.2. The letter was written by a medical representative and the activities and actions of all medical representatives were considered to be promotional under the Code.

Merck Sharp & Dohme had understood that the exemption to Clause 18.2 allowed companies to provide limited numbers of useful items to medical professionals in a setting completely divorced from promotion. It was not intended to allow companies to circumvent the £6 plus VAT rule for gifts/promotional aids by sending out large quantities of more expensive 'educational items' and delivering them via the representative. Such activities completely undermined the £6 plus VAT limit. Merck Sharp & Dohme believed that the method by which this item was distributed at the very least allowed the possibility that its delivery could be linked with a promotional opportunity.

### RESPONSE

GlaxoSmithKline stated that the textbook was provided as a service to medicine and that every aspect of its nature and supply complied with the letter and the spirit of the Code.

The book had been distributed in the same way since March 2003 and GlaxoSmithKline intended to continue in this way for the foreseeable future.

GlaxoSmithKline submitted that the Oxford Handbook of General Practice was clearly of great interest to general practitioners; it did not refer to GlaxoSmithKline or its medicines. GlaxoSmithKline believed it was a high value educational text with no promotional content. It was delivered to the practice exactly in the state it left the printers, with no additional labels, stickers or accompanying letters.

While the value of the textbook was clearly more than £6 (the unit price to GlaxoSmithKline was £13.77, the retail cost was approximately £25) GlaxoSmithKline believed that it should be considered as an item of service to medicine. As such GlaxoSmithKline believed that it fell outside the definition of Clause 18.2 (as a promotional aid of less than £6 in value) but fell within the definition of Clause 18.4 as a medical service which could enhance patient care and benefit the NHS since:

- the book and associated materials did not refer to any medicine brand name;
- the value was greater than £6;
- the book was a non-promotional, independently produced reference text from a reputable publisher by reputable independent authors;
- GlaxoSmithKline had no part or influence in the

production or content of the book;

- the book was a genuinely useful text for a GP to refer to, to improve patient care.

The supplementary information to Clause 18.2 stated:

‘Certain independently produced medical/educational publications such as textbooks have been held to be acceptable gifts under Clause 18.2 .... It might be possible to give certain medical/educational publications in accordance with Clause 18.4 – Provision of Medical and Educational Goods and Services’.

GlaxoSmithKline believed therefore that the textbook in question was an appropriate item to provide to GPs as a service to medicine and it believed the way the book was provided complied with Clause 18.4 and its supplementary information. The item had been appropriately certified under Clause 14 as such.

The process whereby the letter in question was sent to a practice and the subsequent delivery of the textbook was as follows:

- the local GlaxoSmithKline representative chose which GPs would receive the letter offering the textbook;
- the representative generated a mailing from a third party mailing house which sent the letter to the GP’s surgery address. The letter contained only a GlaxoSmithKline logo and no brand logos or product mentions; asked the GP to respond if interested; clearly stated that there was no obligation to see a representative; asked the GP the best time for the representative to call should a call be desired and had been appropriately signed off as defined in the Code by a commercial and medical signatory;
- if the GP wanted a textbook, the representative was notified and ordered it;
- the representative then delivered the book to the practice:
  - representatives were trained to not insist on seeing a doctor to deliver an item and to leave the item with receptionists if required;
  - this training was underpinned by a briefing document, a copy of which was provided;
  - this guidance was available to every representative via an icon on their laptops and had been covered in Code of Practice training updates with field based staff.

In summary GlaxoSmithKline believed the provision of the Oxford Handbook of General Practice was a valid service to medicine as defined in the Code. Neither the book nor any associated mailing had any brand mention or logo associated with it. The book and letters were appropriately certified under the Code.

The book was delivered by a representative who had been trained and who had guidance to avoid the book being used or perceived as being used as an incentive to see a GP.

GlaxoSmithKline believed the letter and textbook complied with the spirit and letter of the Code.

## PANEL RULING

The Panel noted that the letter at issue was dated 9 February 2006 and so the textbook was offered before changes made in the 2006 Code came fully into operation. The relevant requirements were similar in both the 2003 and the 2006 Codes.

The Panel noted that companies were allowed to provide gifts in the form of promotional aids provided that such gifts were inexpensive (no more than £6 plus VAT cost to the company) and relevant to the practice of the recipient’s profession or employment. The 2006 Code stated that the perceived value to the recipient must be similar. Clearly the textbooks at issue were relevant to a doctor’s profession but as each one had cost GlaxoSmithKline more than £6 plus VAT then they could not be regarded as promotional aids.

The 2003 Code, however, allowed companies to provide medical and educational goods and services which enhanced patient care or benefited the NHS. The 2006 Code stipulated that goods and services which benefited the NHS must maintain patient care. These items could cost more than £6 plus VAT. The textbook could be an appropriate medical good. To benefit from this exemption, however, the books must not be provided in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine. The Panel considered that the manner of the provision of medical and educational goods and services should be clearly differentiated from the provision of promotional aids. If this were not so then companies could distribute any items costing more than £6 plus VAT via their sales force and just claim that they were medical and educational goods and services. The relevant supplementary information to Clause 18.1 in the 2003 Code (Clause 18.4 in the 2006 Code) stated that companies should consider using staff other than representatives and that if representatives provided, delivered or demonstrated medical and educational goods and services this must not be linked to the promotion of medicines.

The Panel noted that representatives were inextricably linked to the provision and distribution of the textbooks. The representatives chose which doctors would be offered the books, signed the letters offering the books and then offered to deliver the books. The principal role of a representative was to call on doctors in relation to the promotion of medicines. In that regard the Panel considered that the way in which the textbooks had been provided did not meet the requirements for the provision of medical or educational goods or services and thus a breach of Clause 18.1 of the 2003 Code was ruled.

**Complaint received**                      **16 March 2006**

**Case completed**                              **25 April 2006**