PRIMARY CARE TRUST HEAD OF PRESCRIBING AND MEDICINES MANAGEMENT v PFIZER

Promotion of Champix

The head of prescribing and medicines management at a primary care trust (PCT) complained about the promotion of Champix (varenicline) by Pfizer, referring particularly to an invitation sent by Pfizer to attend a 'new treatment launch update' meeting which she believed breached the spirit if not the letter of the Code.

The complainant was concerned that materials devised for GPs were not suitable for NHS administrative staff. Specialists in smoking cessation came from a wide variety of backgrounds, but most were not members of regulated health professions, and in that respect might be considered to be managerial or administrative staff. These individuals were not able to interpret the content of the draft summary of product characteristics (SPC) which had been attached with the invitations, or to apply its content (for instance in respect of renal impairment etc) in any discussions with members of the public.

It was clear from the invitation that the true purpose of the meeting was to prime smoking cessation advisers to encourage members of the public to ask their doctors or other prescribers to prescribe Champix. The complainant believed this was a clear breach of the Code.

The Panel noted that the Code applied, *inter alia*, to the promotion of medicines to members of the UK health professions and to appropriate administrative staff. Health professionals included members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities might prescribe, supply or administer a medicine. Appropriate administrative staff were not defined in the Code but advice about promotion to them was given in the supplementary information.

The meetings were arranged at the request of the regional tobacco policy manager, who had also selected the attendees. The Panel did not accept Pfizer's contention that, together with the job titles of the delegates, such a selection process was more than adequate justification for their attendance. Irrespective of the involvement of the regional tobacco policy manager Pfizer was responsible for ensuring that the arrangements including the selection of invitees complied with the Code. The Panel noted that a broad group of individuals were invited to attend the meeting, including employees and advisors of all Stop Smoking Service contacts in the region. The Panel noted Pfizer's estimate that 95% of attendees at the first meeting qualified as health professionals in that they were 'involved in seeing patients involved in giving up smoking'. However, the Panel noted that such individuals did not, in the course of their professional activities, prescribe, supply or administer a medicine and thus did not meet the definition of a health professional in the Code.

The Panel noted that the attendees were part of, or very closely linked to, services to support smoking cessation. Roles would vary but many of the attendees would be involved in giving advice and information about medicines either to those trying to stop smoking or to health professionals. The Panel considered that in these circumstances it was not unreasonable to provide clinical information to the attendees who if not health professionals would be appropriate administrative staff. The presentations used at the meeting had been developed specifically to meet the needs of the audience. The material did not advertise a prescription only medicine to the general public. It was not inappropriate to advertise Champix to the attendees. No breach of the Code was ruled.

The head of prescribing and medicines management at a primary care trust (PCT) complained about the promotion of Champix (varenicline) by Pfizer Limited.

COMPLAINT

The complainant referred to an invitation sent by Pfizer to attend a 'new treatment launch update' meeting which she believed breached the spirit if not the letter of the Code.

The complainant was concerned that materials devised for GPs were not suitable for NHS administrative staff. Specialists in smoking cessation came from a wide variety of backgrounds, but most were not members of regulated health professions, and in that respect might be considered to be managerial or administrative staff. These individuals were not able to interpret the content of the draft summary of product characteristics (SPC) which had been attached with the invitations, or to apply its content (for instance in respect of renal impairment etc) in any discussions with members of the public.

The invitation made clear that the true purpose of the meeting was so that smoking cessation advisers could be primed for the purpose of encouraging members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine (Champix). The complainant believed this was a clear breach of Clause 20.2 of the Code.

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 2, 9.1 and 12.1 of the Code in addition to Clause 20.2 as referred to by the complainant.

RESPONSE

Pfizer stated that the invitation for this regional meeting was sent out on 3 November 2006. Champix had received its marketing authorization on 26 September 2006.

The intended audience for the meeting, as stated on the invitation, was NHS Stop Smoking Services staff and other interested stakeholders in smoking cessation, specifically pharmacists, doctors and nurses who were responsible for providing smoking cessation advice and services in the region. The NHS Stop Smoking Services were staffed by trained personnel, nurses and pharmacists. The Statistics on NHS Stop Smoking Services in England, April to June 2006, stated:

'The NHS Stop Smoking Services were set up in Health Action Zones in 1999/00 and rolled out across all Health Authorities in England in 2000/01. The services offer support to help people quit smoking. This can include intensive support through group therapy or one-to-one support. The support is designed to be widely accessible within the local community and is provided by trained personnel such as specialist smoking cessation advisers, trained nurses and pharmacists. The services complement the use of smoking cessation aids Nicotine Replacement Therapy (NRT) and bupropion (Zyban).'

Specifically, the invitation was sent to all Stop Smoking Services contacts in the region, including their employees/advisers, ie administrative staff, the 'alliance leads' and the Smoking in Pregnancy Network. At the first meeting on 30 November, there were 47 attendees after 54 had accepted the invitation. From the list Pfizer estimated that 95% of the attendees were health professionals in that they were involved in seeing patients involved in giving up smoking. Pfizer considered therefore that this was a valid group of health professionals to be in receipt of the presentations. Copies were provided. Pfizer explained that the varenicline clinical overview was similar to a presentation made to smoking cessation advisors at a recent advisory board and had been tailored to the intended audience in response to feedback from that meeting. The presentation by a GP represented his own views. The content was devised as a result of discussion between himself and Stop Smoking Services. Pfizer had had no editorial control over the content other than to ensure it complied with the Code.

Pfizer believed therefore that the meetings and the materials complied with the Code. The invitation did not, as the complainant alleged, make it clear that the 'true purpose of the meeting is so that smoking cessation advisers can be primed "for the purpose of encouraging members of the public to ask their doctors or other prescribers to prescribe a specific prescription only medicine (Champix)"'. On the contrary, Pfizer maintained that the invitation and the materials presented were developed specifically to place varenicline appropriately in the context of antismoking treatment modalities. Furthermore, as the meetings were designed for and given to health professionals and their appropriate administrative colleagues, Pfizer strongly refuted the complainant's accusation. Pfizer denied, therefore, any breach of Clause 20.2.

Pfizer believed that the invitation was distributed to a highly relevant category of recipients whose need for and interest in this topic and the information given could reasonably be assumed. High standards had been maintained in the development of these materials and in the preparation of the meetings. Pfizer asserted that nothing had occurred in the context of these meetings that could be construed as bringing discredit upon, or reducing confidence in, the pharmaceutical industry. Pfizer was confident that these meetings and materials did not breach Clauses 2, 9.1 or 12.1.

In response to a request for further information Pfizer provided copies of the delegate list for the meetings with the requested status and role of each attendee. Pfizer noted that from the designations of the attendees set out in this list, at least 95% of the attendees qualified as health professionals under Clause 1.4 of the Code as they consulted with patients who were giving up smoking and might 'prescribe, supply or administer a medicine'. The remaining few attendees were appropriate NHS administrative staff with a relevant interest in smoking cessation therapy, for whom provision was made under Clause 1.1 of the Code.

Pfizer did not have access to details of the qualifications and training of individual attendees. Indeed, it was not Pfizer's standards practice to seek the definition of (or supporting evidence for) the qualifications or training background of health professionals or appropriate administrative staff. Pfizer believed that the job titles of the attendees, as well as the fact that they were selected as appropriate attendees by the regional tobacco policy manager (RTPM), a senior public officer with responsibility for implementation of the Department of Health Stop Smoking Policy, was more than adequate justification for their attendance.

By way of further background, these meetings were arranged at the request of the RTPM to provide a medical presentation on varenicline to frontline staff involved in the provision of smoking cessation advice to patients. Suitable invitees were identified. This list was then scrutinised and approved. Invitations were then sent out by the RTPM. It was understood by Pfizer and the RTPM that invitees, as NHS Stop Smoking Services staff, would be involved in the provision of smoking cessation advice, including advice on and provision of medication to support smoking cessation, and they therefore fulfilled the definition of health professional given in Clause 1.4 of the Code. The invitation was also extended (at the discretion of the RTPM) to invitees outside of the NHS Stop Smoking Services who provided similar smoking

cessation services, including pharmacists, GPs, and in this case, the Smoking in Pregnancy Network. The invitations were approved via the Pfizer promotional approval process, and it was clear that the invitation was intended only for 'frontline' staff seeing patients.

PANEL RULING

The Panel noted that the Code applied, *inter alia*, to the promotion of medicines to members of the UK health professions and to appropriate administrative staff (Clause 1.1). Clause 1.4 explained that a health professional included members of the medical, dental, pharmacy and nursing professions and any other persons who in the course of their professional activities might prescribe, supply or administer a medicine. Appropriate administrative staff were not defined in the Code but advice about promotion to them was given in the supplementary information to Clause 1.1 Promotion to Administrative Staff.

The Panel noted that the meetings were arranged at the request of the RTPM, who had also selected the attendees. The Panel did not accept Pfizer's contention that, together with the job titles of the delegates, such a selection process was more than adequate justification for their attendance. Irrespective of the involvement of the RTPM Pfizer was responsible for ensuring that the overall arrangements including the selection of invitees complied with the Code. The Panel noted that a broad group of individuals were invited to attend the meeting including employees and advisors of all Stop Smoking Service contacts in the region. The Panel noted Pfizer's estimate that 95% of attendees at the first meeting on 30 November qualified as health professionals in that they were 'involved in seeing patients involved in giving up smoking'. However, the Panel noted that such individuals did not, in the course of their professional activities, prescribe, supply or administer a medicine and thus did not meet the definition of a health professional set out in Clause 1.4.

The Panel noted Pfizer's submission that invitees would be involved in the provision of smoking cessation advice. The Panel considered that staff supporting patients on medication within the context of smoking cessation might qualify as appropriate administrative staff under Clause 1.1 of the Code. The Panel noted that the meeting on 30 November included an administrator and a marketing and service development manager. Similarly, the meeting on 8 December included an administrator, an administration manager and a co-ordinator. The status of one delegate, was not stated. Health professionals also attended. The Panel noted that whilst those involved in health administration etc in certain circumstances could qualify as appropriate administrative staff, promotional material had to be relevant to their role; for example, practice managers could attend a company presentation on practice management.

The Panel noted that one presentation, entitled 'Smoking Cessation Efficacy and Safety of an α4ß2 Nicotinic Acetylcholine Receptor Partial Agonist: Varenicline Tartrate' discussed in detail varenicline's mechanism of action, detailed clinical data, including comparative data, a patient support programme and ongoing clinical studies. The Panel noted Pfizer's submission that this presentation had been tailored to the audience after a similar one had been shown to smoking cessation advisors at an advisory board. The second presentation 'Working with varenicline in practice' primarily discussed how to ensure delegates' PCTs had sufficient clinical and financial information to make funding decisions. Two slides discussed the management of clients' expectations of new treatments with reference to varenicline. One slide discussed general practices working with the NHS Stop Smoking Services. The content of this presentation had been devised as a result of discussions between the presenter and Stop Smoking Services.

The Panel noted that the attendees were part of, or very closely linked to, services to support smoking cessation. Roles would vary but many of the attendees would be involved in giving advice and information about medicines either to those trying to stop smoking or to health professionals. The Panel considered that in these circumstances it was not unreasonable to provide clinical information to the attendees who if not health professionals would be appropriate administrative staff. The presentations used at the meeting had been developed specifically to meet the needs of the audience. Thus the Panel ruled no breach of Clause 12.1. The material did not advertise a prescription only medicine to the general public. It was not inappropriate to advertise Champix to the attendees. Thus no breach of Clause 20.2 was ruled.

Given its rulings of no breach the Panel did not consider that Pfizer had failed to meet high standards and no breach of Clause 9.1 was ruled.

Complaint received 15 November 2006

Case completed 20 February 2007