

CONSULTANT IN PUBLIC HEALTH v PFIZER

Promotion of Champix

A lead consultant in public health at a primary care trust (PCT) alleged that the tactics Pfizer used to promote Champix (varenicline) were premature and unethical.

The complainant noted that Pfizer had organised a meeting for GPs, practice managers and, in particular, stop smoking advisors working in community pharmacies accredited by the local stop smoking service to provide stop smoking advice. Attendees received a pad of letters, clearly aimed at prescribers, which stated that the client was receiving a support programme from the local stop smoking service. Further promotion of Champix and the distribution of the letter had taken place in other local areas. This was clearly part of a concerted campaign.

The complainant was particularly concerned that the meeting had taken place before the publication of the definitive National Institute for Health and Clinical Excellence (NICE) guidance and thus in disregard of due process. The company had tried to ride roughshod over the gold standard therapy of nicotine replacement therapy (NRT), a determination that was currently unchanged by the draft NICE guidance. This meeting was organised without the courtesy of informing the local PCT or stop smoking service.

The Panel noted that Pfizer had organised a meeting in June 2007 to promote Champix to health professionals with an interest in smoking cessation. Champix had received its marketing authorization in September 2006 from when Pfizer was entitled to promote the product. It was immaterial in that regard that NICE had yet to issue guidance about the use of Champix. The Panel thus did not consider that Pfizer had prematurely promoted Champix. No breach of the Code was ruled.

The Panel noted that the slide kit used at the meeting in question did not refer to local guidelines and although it focussed on Champix it did, *inter alia*, detail the efficacy of NRT. The Panel thus did not consider that there was any evidence to show that Pfizer had either tried to wilfully obstruct locally agreed guidelines for the prescribing of medicines for smoking cessation, or tried to ride roughshod over the use of NRT as alleged. No breach of the Code was ruled.

The Panel noted that although Pfizer had not been in direct contact with the complainant it had talked to the team leader of the local stop smoking service who reported directly to the complainant. The Panel considered that Pfizer had consulted locally and had not acted without the courtesy of informing the local PCT or stop smoking service as alleged although the Code did not specifically require such actions. No breach of the Code was ruled.

A lead consultant in public health at a primary care trust (PCT), with responsibility for co-ordinating the local stop smoking service, complained about the promotion of Champix (varenicline) by Pfizer Limited.

COMPLAINT

The complainant alleged that Pfizer's tactics in relation to the promotion of Champix were premature and unethical. The company had organised a meeting for GPs, practice managers and in particular stop smoking advisors working in community pharmacies accredited by the local stop smoking service to provide stop smoking advice. Attendees received a pad of letters, clearly aimed at prescribers, which stated that the client was receiving a support programme from the local stop smoking service. Further promotion of Champix and the distribution of the letter had taken place in other local areas. This was clearly part of a concerted campaign.

The complainant was particularly concerned that: Champix had been promoted notwithstanding that the National Institute for Health and Clinical Excellence (NICE) had yet to definitely advise that it was an appropriate therapy ie the meeting had taken place before the publication of the definitive NICE guidance and thus in disregard of due process. Further, the complainant alleged that Pfizer sought to wilfully obstruct professionally determined, locally agreed guidelines for the prescribing of pharmacological interventions for stop smoking. Specifically the company had tried to ride roughshod over the gold standard of nicotine replacement therapy (NRT), a determination that was currently unchanged by the draft NICE guidance. Finally, the complainant noted that the meeting was organised without the courtesy of informing the local PCT or stop smoking service.

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 2 and 9.1 of the Code.

RESPONSE

Pfizer noted that the meeting in question, which was a follow on to other such meetings in the area, had been organised at the request of local health professionals with an interest in smoking cessation and included GPs, pharmacists, local smoking cessation advisors and nurses. The main objective of the meeting was to increase the awareness of Champix as a new form of treatment for smoking cessation in adult smokers.

During the meeting Pfizer made a presentation to the eighteen delegates using the Champix customer slide kit. This was an internally approved slide kit for use by the field force which had been pre-vetted by the Medicines and Healthcare products Regulatory Agency (MHRA). The slide kit detailed Champix's mechanism

of action, clinical data including comparative data, information about a patient support programme and ongoing clinical studies.

Before the presentation the delegates were given the 'GP referral aid' which was what Pfizer assumed the complainant had referred to and was used by the smoking cessation advisor and other health professionals during the appointment with the patient. By using the checklist provided the patients were assessed by the health professional. The tear-off aid sheet was then given to the patient and they were advised to give it to their GP at their next appointment. This review would help the GP when he/she examined the patient.

This process confirmed that the local stop smoking service had seen the patient and referred them to the GP. This ensured that the stop smoking service was being used properly, and further ensured that these patients would continue to receive the behavioural support from the service which formed an important part of the smoking cessation treatment approach with Champix.

As in every other meeting (seven in total including the one in question) for the local PCT, the locally agreed guidelines were not discussed, nor did any discussion take place on superiority over NRT. Pfizer representatives did discuss that where smokers might have failed on current therapies (NRT and Zyban (bupropion)) then Champix might be of benefit.

Pfizer had always behaved in a professional and sensitive manner, keeping in mind local guidelines, and would continue this professional approach in the future.

Pfizer noted that the meeting was held on 14 June 2007. Champix received its UK marketing authorization on 26 September 2006 which enabled it to start promoting the product to health professionals in accordance with Clause 3 of the Code. Pfizer ensured that it promoted its medicines within the ethical framework set by the Code. The intended audience for the meeting, as stated on the invitation, was NHS stop smoking services staff and other stakeholders interested in smoking cessation, specifically pharmacists, doctors and nurses who were responsible for providing smoking cessation advice and services in the region.

On 14 December 2006, the Department of Health circulated a best practice guidance document on the implementation of NICE guidance. The document reiterated, clarified and explained in more detail the original guidance relating to the introduction of new healthcare interventions and the funding direction applying to NICE technology appraisals. The document stated: 'It is not acceptable to cite a lack of NICE guidance as a reason for not providing treatment. A key role of the NHS is to make decisions about the use of new interventions and this has always been the case, long before NICE was established.'

Pfizer stated that for at least four of the seven meetings the local stop smoking service was invited to present its views. The team leader for the service, who reported directly to the complainant, attended the first meeting.

As the stop smoking service team and locality leads had seen this presentation before and had not asked to see it again, they were not invited to the meeting on 14 June. This meeting was held for those team leaders and smoking cessation advisors that had not previously seen the presentation.

Pfizer had tried, unsuccessfully, several times to talk to the complainant. Based on this Pfizer kept in touch with the team leader of the local stop smoking service, and had always asked her to inform and invite the complainant to all of its meetings. Indeed, Pfizer had been in touch with all of the local stop smoking leads.

Pfizer considered that throughout it had behaved in an open and honest manner; it absolutely refuted the complainant's comments and regretted very much that he had chosen to express his views in this way. Pfizer had not promoted Champix outside its product licence and had complied with both the spirit and the letter of the Code. Pfizer concluded that it had not breached Clause 9.1 or Clause 2 and it was confident that its conduct had been of a high standard throughout.

PANEL RULING

The Panel noted that Pfizer had organised a meeting in June 2007 to promote Champix to health professionals with an interest in smoking cessation. Champix had received its marketing authorization in September 2006 from when Pfizer was entitled to promote the product. It was immaterial in that regard that NICE had yet to issue guidance about the use of Champix. The Panel thus did not consider that Pfizer had prematurely promoted Champix. No breach of Clause 9.1 was ruled.

The Panel noted that the slide kit used at the meeting in question did not refer to local guidelines and although it focussed on Champix it did, *inter alia*, detail the efficacy of NRT. The Panel thus did not consider that there was any evidence to show that Pfizer had either tried to wilfully obstruct locally agreed guidelines for the prescribing of medicines for smoking cessation, or tried to ride roughshod over the use of NRT as alleged. No breach of Clause 9.1 was ruled.

The Panel noted Pfizer's submission that although it had not been in direct contact with the complainant it had talked to the team leader of the local stop smoking service who reported directly to the complainant. The Panel considered that Pfizer had consulted locally regarding its promotional activities and intent and that it had not acted without the courtesy of informing the local PCT or stop smoking service as alleged although the Code did not specifically require such actions. No breach of Clause 9.1 was ruled.

The Panel noted its rulings above and considered that there was no reason to rule a breach of Clause 2 of the Code, a ruling which was a sign of particular censure and reserved for such use.

Complaint received	28 June 2007
Case completed	15 August 2007