# PRIMARY CARE TRUST PHARMACIST v GW PHARMACEUTICALS

## Alleged promotion of Sativex

**A prescribing support pharmacist with a primary care trust (PCT) was concerned that GW Pharmaceuticals was trying to promote its unlicensed product, Sativex (a cannabis derivative), to the public. The complainant provided a copy of a letter written by the local multiple sclerosis (MS) specialist co-ordinator to a practice manager. The letter asked the recipient to let GPs and others know that at a meeting of the local branch of the MS Society there would be a presentation about Sativex given by GW. The complainant understood that MS sufferers would be anxious to have information about a new product which might offer potential benefit but patient expectation of a prescription might be inappropriately raised.**

**The Panel noted that GW had accepted an invitation for one of its employees to speak about Sativex at the meeting; anyone connected with MS, whether patient or practitioner, was welcome to attend. Sativex was unlicensed in the UK. A letter from the MS specialist co-ordinator confirmed that the planned meeting had been cancelled.**

**The Panel was concerned about the proposed arrangements. It was difficult to see that the planned presentation would do anything other than heighten awareness about and stimulate demand for Sativex, an unlicensed medicine. The Panel noted, however, that GW had done no more than accept the invitation to speak; the meeting had been cancelled. No information had been given to the patient group. There was no evidence that high standards had not been maintained. No prescription only or unlicensed medicine had been promoted to the public and nor had patients been encouraged to ask their doctor to prescribe Sativex. No breaches of the Code were ruled.**

A prescribing support pharmacist with a primary care trust (PCT) complained about the promotion of Sativex by GW Pharmaceuticals plc. The complainant provided a copy of a letter written by the multiple sclerosis (MS) specialist co-ordinator to a practice manager. The letter asked the recipient to let GPs and others know that the local branch of the MS Society would be holding a meeting at which there would be a presentation about Sativex (a cannabis derivative) given by the head of research and development at GW.

### COMPLAINT

The complainant was concerned that the planned meeting might breach the Code:

- Prescription only medicines must not be advertised to the public. Non-promotional information could be provided to the public directly or via the media.
- A medicine must not be promoted prior to being authorized for UK use. An exception was factual information made available as advance notification to those responsible for policy decisions, so that the NHS could plan financially.

The complainant understood that MS sufferers would be anxious to have information about a new product which might offer potential benefit but patient expectation of a prescription might be inappropriately raised.

When writing to GW the Authority asked it to respond in relation to the requirements of Clauses 2, 3.1, 9.1, 20.1 and 20.2 of the Code.

### RESPONSE

GW noted that the complaint was about a meeting at which it had been specifically invited to speak. The invitation had come from the MS co-ordinator of a PCT, who had been approached for information from a number of local GPs, the local branch of the MS Society and a local consultant neurologist. This meeting had not yet taken place. GW was surprised that the Authority regarded this complaint as valid, since it referred to a meeting that had not yet occurred, and could only therefore be a complaint against the potential content of such a meeting, or against the fact that a meeting had been arranged at the request of an independent patient organisation and a specialist representative of a PCT.

GW supplied copies of a letter from the organiser of the proposed meeting confirming this invitation and a letter from the secretary of the local branch of the MS Society confirming that the original suggestion for such a meeting came from them. These confirmed that the company had responded to a request for information by a branch of the MS Society and the MS specialist co-ordinator of a PCT.

GW did not solicit such a meeting and indeed went out of its way to tell organisers about the limitations placed on pharmaceutical companies by the Code. In the company's view, however, a research-based pharmaceutical company had an ethical responsibility to supply accurate and up-to-date information to patients and to health care workers who specifically and spontaneously requested it.

GW noted that Sativex was of significant interest to people with MS. The company was always careful to ensure absolute adherence to the Code and as such considered it appropriate to accept unsolicited invitations to meetings and ensured that any information provided at such meetings in response to questions was factual and balanced. GW provided no information or advice to any members of the public on personal medical matters.

GW noted that Sativex was an approved prescription medicine in Canada where it had been available on prescription since July 2005. Sativex was not currently under regulatory review in the UK and there was therefore no prospective date for potential approval.

With regard to Clause 2, GW stated that when a health professional, or a reputable patient organisation requested that it provide information to them regarding the basic research and development status of a new approach to the treatment of a disabling condition, then the company considered that it had a duty so to do. The company sought to ensure at all times that the request to speak was a *bona fide* request and that the organisation understood that it was neither permitted to, nor did it wish to, solicit prescriptions.

With regard to the meeting in question, GW considered that in responding to a *bona fide* request from the MS co-ordinator of a PCT, coupled with a request from the secretary of the local branch of the MS Society, it had behaved responsibly and ethically. Indeed, the company considered that to fail to provide accurate information in response to such a request would be irresponsible. GW therefore contended that acceptance of the invitation to provide information at this meeting did not in any way bring the industry into disrepute.

With regard to Clause 3.1, GW stated that acceptance of an invitation to provide information at a meeting could not on its own be regarded as promotion, since no exchange of information had taken place. The company did not consider that the legitimate exchange of medical and scientific information during the development of a medicine – especially a medicine with the level of public interest that Sativex had engendered – was prohibited under the Code. With the meeting in question there was no involvement of GW in the planning, financing, issuing of invitations, agenda (in fact, the company had not seen the agenda for the meeting), or sponsorship of the meeting in any way.

GW was unclear in what way it might be considered not to be exhibiting high standards in breach of Clause 9.1. The planned exchange of information had not taken place, so the only way in which it could be guilty of failing to exhibit high standards could be in accepting an invitation to speak at a meeting proposed and organised by the MS co-ordinator of a PCT, and at the request of the secretary of a local branch of the MS Society.

As stated above, GW had not been involved in any aspect of the planning or execution of the proposed meeting, and it had not given any undertaking to provide funding or to accept payment. The company logo had not to its knowledge been used in the documentation associated with the meeting.

GW repeated that, in its view, an ethical and responsible company had a duty to provide factual and accurate information in response to *bona fide* requests for such.

With respect to Clause 20.1, GW stated that no promotional activity had taken place, and no meeting had taken place, so no information had been exchanged. Again, the only way in which the company could be promoting would be by accepting an invitation to present scientific and clinical information regarding a medicine under active development. As stated above, GW had not been involved in any way in the sponsorship or support of this meeting, and there was no financial involvement of the company in any way.

With regard to Clause 20.2, GW stated that MS patients were very interested in the development of new and promising approaches to the treatment and management of their condition. The company had a constructive relationship with the MS Society in this regard and considered it appropriate to provide, in response to an unsolicited request, an update on its scientific progress in the Society's research area of interest. Similarly, there was a high level of interest in the progress of potential new MS treatments among the medical community. For this community also, GW considered it appropriate to provide factual information in response to *bona fide* requests. GW undertook no sponsorship of patient groups, it had no stands at meetings, it provided no samples etc.

Furthermore, in responding to requests from patient organisations and healthcare organisations or individuals, GW was careful to state that it was not permitted to solicit either such meetings, or prescriptions for Sativex, although its understanding was that it was permitted to solicit relevant physicians regarding their inclusion in clinical trials.

All GW had done in respect of the meeting at issue was to accept an invitation to provide information; it was difficult to see how this could constitute a breach of the Code.

In summary, the extent of GW's involvement had been to accept what it regarded as a *bona fide* invitation to provide medical and scientific information to a group of interested parties with a strong and legitimate interest in the company's research. The company's understanding of the Code was that this was a legitimate exercise. The company would be surprised if its agreement to accept an invitation to this meeting was not permissible under the Code.

## PANEL RULING

The Panel noted that GW had been invited to speak at a meeting of a local branch of the MS Society; anyone connected with MS, whether patient or practitioner, was welcome to attend. GW had accepted the invitation and one of its employees planned to give a talk on Sativex. Sativex was unlicensed in the UK. The Panel had some sympathy with a local branch of a patient organization wanting to find out more about new medicines that might become available but nonetheless noted that in meeting such requests companies still had to conform with the requirements of the Code. Patients' wishes could not override the Code. A letter from the MS specialist co-ordinator confirmed that the planned meeting had been cancelled.

The Panel noted that Clause 3.1 stated that a medicine must not be promoted prior to the grant of the marketing authorization which permitted its sale or supply. Clause 20.1 prohibited the advertising of prescription only medicines to the general public. Clause 20.2 of the Code permitted information about prescription only medicines to be supplied directly or indirectly to the general public but such information

had to be factual and presented in a balanced way. It must not raise unfounded hopes of successful treatment or be misleading with respect to the safety of the product. Statements must not be made for the purpose of encouraging members of the public to ask their health professional to prescribe a specific prescription only medicine.

The Panel was concerned that an employee of GW had planned to give a talk on Sativex to members of the public at a local branch meeting of the MS Society. It was difficult to see that such a presentation would do anything other than heighten awareness about and stimulate demand for Sativex, an unlicensed medicine. Whilst it was not necessarily unacceptable for companies to present at patient group meetings they should exercise extreme caution when embarking on such activity and take great care to ensure that all of the arrangements complied with the Code, especially the provisions of Clause 20. Talking about specific medicines to such groups would leave companies vulnerable with regard to the Code.

The Panel noted that in this case GW had done no more than accept the invitation to speak; the meeting had been cancelled. No information had been given to the patient group. There was no evidence that high standards had not been maintained. No prescription only or unlicensed medicine had been promoted to the public and nor had patients been encouraged to ask their doctor to prescribe Sativex. No breach of Clauses 2, 3.1, 9.1, 20.1 and 20.2 was ruled.

**Complaint received** **26 April 2006**

**Case completed** **11 July 2006**