

THE SUNDAY TIMES/DIRECTOR AND A GENERAL PRACTITIONER v WYETH

Sponsored nurses

An article entitled 'Nurses earn bonuses for use of latest drugs', which appeared in The Sunday Times, criticized the activities of, *inter alia*, Wyeth. In accordance with established practice the matter was taken up by the Director as a complaint under the Code (Case AUTH/1808/3/06).

The article stated that Wyeth had paid nurses through an agency to conduct free audits in GP surgeries to identify patients with conditions such as asthma or diabetes who might benefit from a new medicine. The nurses were paid a salary and usually a bonus which was linked to the number of patients or records they saw. The article also stated that the nurses were described in promotional literature as being able to 'influence' new prescriptions for the benefit of their pharmaceutical companies. The nurses were routinely backed up by sales teams.

A general practitioner subsequently complained about the involvement of Wyeth in providing nursing advisors as detailed in The Sunday Times (Case AUTH/1811/3/06). The complainant was greatly concerned about the nurse advisors because they had a conflict of interest to promote a particular product. The Sunday Times had assured the complainant that the story was correct. The GP alleged that it was a clear admission that these nurse advisors were not independent but were involved in the marketing of medicines. A breach of the Code was alleged.

Wyeth stated that it currently offered one audit service in primary care, the GastroCare Service.

The Panel noted that the GastroCare service provided a review of patients' medication in line with the prescribing decisions of the GP. Representatives' briefing material stated that the service and the promotion of Wyeth's products must not be linked in any way. In addition the service had to be freely offered ie to all customers. Representatives could not restrict the offering or steer customers to a specific choice. The GPs must make the decision having been given full details of all options available. The detail flow for Zoton FasTab did not refer to the GastroCare service. At least 10 working days had to elapse either before or after a call to promote or discuss Wyeth's products and a call to discuss the GastroCare Service. The Panel did not consider that the service was an inducement to prescribe, supply, administer,

recommend or buy any medicine. No breaches of the Code were ruled including no breach of Clause 2.

An article entitled 'Nurses earn bonuses for use of latest drugs', which appeared in The Sunday Times, criticized the activities of, *inter alia*, Wyeth Pharmaceuticals Ltd. In accordance with established practice the matter was taken up by the Director as a complaint under the Code (Case AUTH/1808/3/06).

A general practitioner in Glasgow, subsequently complained about the involvement of Wyeth in providing nursing advisors as detailed in The Sunday Times (Case AUTH/1811/3/06).

COMPLAINT

The article stated that Wyeth had paid nurses through an agency to conduct free audits in GP surgeries to identify patients with conditions such as asthma or diabetes who might benefit from a new medicine. The nurses were paid a salary and usually a bonus which was linked to the number of patients or records they saw.

The article also stated that the nurses were described in promotional literature as being able to 'influence' new prescriptions for the benefit of their pharmaceutical companies. The nurses were routinely backed up by sales teams.

A recruitment consultant had told an undercover reporter that the job of the nurses was to identify patients with a specific condition '[it] opens the doors to a medical representative. They come in and close the business'.

The complainant (Case AUTH/1811/3/06) was greatly concerned by involvement of these nurse advisors because they had a conflict of interest to promote a particular company product. The complainant stated that he had contacted The Sunday Times which had transcripts of conversations between a reporter and an agency representative. The Sunday

Times had assured the GP that the story was correct. The GP alleged that it was a clear admission that these nurse advisors were not independent but were involved in the marketing of medicines. The complainant alleged that this was in breach of the Code. The complainant requested that the Panel consider halting any current nurse advisor activity until this case had completed.

Wyeth was asked to respond in relation to Clauses 2, 9.1 and 18.1 of the Code.

RESPONSE

Wyeth submitted that it currently offered one audit service in primary care, the GastroCare Service. This service provided GP practices with the resource to implement National Institute of Health and Clinical Excellence (NICE) and Scottish Intercollegiate Guidelines Network (SIGN) dyspepsia guidelines, with a view to ensuring patients received optimal treatment following a clinical assessment by the practice. The GastroCare Service did not promote any specific product nor did it lead automatically to a Wyeth product being prescribed. The GastroCare Service was offered without any condition that a Wyeth product would be prescribed or indeed that any medicine would be prescribed at all. The practice was asked to indicate in writing its treatment plan before the audit commenced and all treatment decisions arising out of the audit rested solely with the practice. The practice might change its treatment decisions during the audit.

Wyeth submitted that the GastroCare Service consisted of three different audit options. Copies of the materials describing each option for GPs were provided (including Upper GI Audit & Review; NSAID Audit & Review; *H. pylori* Eradication Test & Treat Audit & Review). These documents clearly explained the aim of the audit service and what it involved. The documents were currently in the process of being reviewed and certified in relation to the new requirements of the 2006 Code.

Roles of sales representatives, nurses, the agency and GPs

Wyeth submitted that its GastroCare Service was offered to practices by its sales representatives. If a practice was interested in undertaking the audit, the representative arranged a date for a registered nurse to attend that practice in order to implement the GastroCare Service. If requested by a practice, the nurse would also attend an introductory meeting with the practice. The nurse would not have contact with a practice unless this arrangement was put in place by the representative. Representatives could have no further involvement in the process once the booking and consent form had been signed by the practice and were not permitted to visit the practice to promote Wyeth products whilst the nurse was implementing the GastroCare Service at that practice.

Wyeth submitted that it had a contract with an agency for it to provide nurses for the GastroCare Service. These nurses were employed by the agency and it was, therefore, responsible for matters such as remuneration.

Wyeth submitted that the representatives and nurses had been given a briefing document to set out the scope of their respective roles. The GastroCare Service briefing document was provided. The role of the representative was also governed by a Wyeth standard operating procedure. In accordance with the Code, the Nursing & Midwifery Council (NMC) Code of professional conduct and Wyeth policies and procedures, the briefing document made it clear that the nurses must not be involved in product promotion. The role of the GastroCare nurse was only to implement the GastroCare Service in accordance with the requirements of the practice. As stated above, GPs were asked to indicate in writing their treatment management plan before the audit commenced and all treatment decisions arising out of the audit rested solely with the GPs.

Wyeth submitted that the agency's literature placed considerable weight on its nurses complying with the ABPI Code and the NMC Code of professional conduct.

Nurse remuneration

Wyeth reiterated that the agency was responsible for remuneration of the GastroCare nurses. Remuneration consisted of a salary and eligibility to an incentive scheme under which the nurses might qualify for a bonus. Salary fell between bands 6 and 7 of NHS nurse salaries, which was consistent with the level and status of the nurse. The incentive scheme was designed to recognise the amount of work carried out in an audit by a nurse and was specifically based on the numbers of notes a nurse would have to review in any audit programme. The bonus was not linked in any way to either audit outcomes or to local or national sales of a specific product or products. The supplementary information to Clause 18.4 of the 2006 Code stated 'Bonus schemes linked to a company's overall national performance, or to the level of service provided, may be acceptable'. Given that the agency's incentive scheme was linked to the level of service provided, both the agency and Wyeth considered that the scheme was acceptable under the Code.

Therefore, for the reasons indicated above, Wyeth submitted that its arrangements for the current GastroCare Service complied with the requirements of Clause 18.4 of the 2006 Code (as noted, the arrangements were currently under review having regard to the requirements newly introduced by the 2006 Code and revised materials for the GastroCare Service would be introduced shortly). Further, Wyeth submitted that, in relation to the GastroCare Service, it had maintained high standards at all times and had not done anything to discredit or reduce confidence in the pharmaceutical industry. Consequently, Wyeth did not accept that it had breached Clauses 2, 9.1 or 18.4 of the Code in relation to the GastroCare Service.

Copies of relevant briefing material for representatives regarding service provision were provided.

PANEL RULING

The Panel noted that these cases were considered in

relation to the 2003 Code using the 2006 Constitution and Procedure.

With regard to therapy review services the supplementary information to Clause 18.4 of the 2006 Code provided helpful guidance. A therapeutic review which aimed to ensure that patients received optimal treatment following a clinical assessment was a legitimate activity for a pharmaceutical company to support and/or assist. The result of such clinical assessments might require, among other things, possible changes of treatment including changes of dose or medicine or cessation of treatment. A genuine therapeutic review should include a comprehensive range of relevant treatment choices, including non-medicinal choices, for the health professional and should not be limited to the medicines of the sponsoring pharmaceutical company. The arrangements for therapeutic review must enhance patient care, or benefit the NHS and maintain patient care. The decision to change or commence treatment must be made for each individual patient by the prescriber and every decision to change an individual patient's treatment must be documented with evidence that it was made on rational grounds.

The supplementary information to Clause 18.1 of the 2003 Code (and the supplementary information to Clause 18.4 of the 2006 Code) stated that if a service required patient identification or contact then the service provider should be appropriately qualified eg a sponsored registered nurse not employed as a medical representative. Sponsored health professionals should not be involved in the promotion of specific products. Nurses were required to comply with the Nursing and Midwifery Council Code of professional conduct which required that registration status was not used in the promotion of medicines.

The remuneration of service providers must not be linked to sales in any particular territory or place or to sales of a specific product or products. Bonus schemes linked to actual performance or to the level

of service provided might be acceptable. The supplementary information to Clause 18.1 of the 2003 Code (and the supplementary information to Clause 18.4 of the 2006 Code) stated that companies must ensure that patient confidentiality was maintained and that data protection legislation was complied with.

The Panel noted that the GastroCare service provided a review of patients' medication in line with the prescribing decisions of the GP. Representatives' briefing material stated that the service and the promotion of Wyeth's products must not be linked in any way. In addition the service had to be freely offered ie to all customers. Representatives could not restrict the offering or steer customers to a specific choice. The GPs must make the decision having been given full details of all options available. The detail flow for a Zoton FasTab detail aid (ZZOT3979) did not refer to the GastroCare service. At least 10 working days had to separate a call to promote or discuss Wyeth's products and a call to discuss the GastroCare Service. Similarly, once a GastroCare service had been completed representatives could not promote Wyeth products at that surgery until a further 10 working days had elapsed. The Panel did not consider that the service was an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of Clause 18.1 of the 2003 Code was ruled. The Panel also ruled no breach of Clause 2 and 9.1 of the 2003 Code.

Case AUTH/1808/3/06

Proceedings Commenced 10 March 2006

Case completed 20 July 2006

Case AUTH/1811/3/06

Complaint received 13 March 2006

Case completed 20 July 2006