

THE SUNDAY TIMES/DIRECTOR AND A GENERAL PRACTITIONER v GLAXOSMITHKLINE

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*, GlaxoSmithKline. In accordance with established practice the matter was taken up by the Director as a complaint under the Code (Case AUTH/1806/3/06).

The article stated that GlaxoSmithKline 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; nurses were said to be rewarded for the number of surgeries they visited or 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 GlaxoSmithKline in providing nursing advisors as detailed in The Sunday Times (Case AUTH/1809/3/06). 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 the nurse advisors were not independent but were involved in the marketing of medicines. A breach of the Code was alleged.

The Panel noted that the documentation for the schemes offered by GlaxoSmithKline ensured that the practice agreed to the arrangements including identifying the search criteria, the inclusion and exclusion criteria to define patients appropriate for review and the treatment options from the full range of therapeutic options. Further each change of treatment had to be authorized and implemented by a GP and the reasons for changes documented.

The Panel considered that the roles of the GlaxoSmithKline promotional staff and non promotional staff appeared to be clearly separated. Where the representatives both promoted medicines and provided detailed information about the service it appeared that this was clearly separated in that the representatives could not carry out both functions at the same visit. This point was covered by the briefing material.

The Panel noted that the remuneration of the nurse advisors was linked to the number of patients seen, the number of clinics run and customer satisfaction; it was not linked to the prescription, supply, administration, recommendation or purchase of any medicine.

The Panel considered that some of the arrangements might be of concern, much would depend on the practice which had control of every step of the process. Provided the nurse advisors complied with their professional codes, and there was no evidence that they had not, it did not appear to the Panel that the arrangements were in general necessarily unacceptable. There was no complaint about any specific arrangements, the complaints concerned the generality of the review services.

Overall the Panel considered that the services offered by GlaxoSmithKline were not unacceptable. The services would enhance patient care. The provision of the services was not linked to the prescription of any specific medicine. The decision of what to prescribe lay with the patient's doctor. The Panel did not consider that the services were an inducement to prescribe, supply, administer, recommend or buy any medicine. No breaches of the Code were ruled including no breach 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*, GlaxoSmithKline UK Limited. In accordance with established practice the matter was taken up by the Director as a complaint under the Code (Case AUTH/1806/3/06).

A general practitioner subsequently complained about the involvement of GlaxoSmithKline in providing nursing advisors as detailed in The Sunday Times (Case AUTH/1809/3/06).

COMPLAINT

The article stated that GlaxoSmithKline 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; nurses were said to be rewarded for the number of surgeries they visited or 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/1809/3/06) was greatly concerned by the 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 the 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 considered halting any current nurse advisor activity until this case had completed.

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

RESPONSE

GlaxoSmithKline noted that The Sunday Times article included the following relevant information: that nurses were provided free to GP surgeries and were given access to patients' medical records to check whether they were on the most up-to-date medicines; that, although barred from promoting the pharmaceutical company's products, 15% of their pay was linked to the number of patients or records they saw; that the nurses were routinely backed up by sales teams; that nurses were described in promotional literature as being able to 'influence' new prescriptions for the benefit of the pharmaceutical companies; that nurse advisors were paid a salary and usually a bonus, with nurses being rewarded for the number of surgeries that they visited and the nurse agency being quoted as paying performance bonuses; that an 'undercover reporter' had been told by a recruitment agency that the nurse's role was to identify patients with a specific condition and this 'opens the doors to a medical representative who come in and close the business'.

GlaxoSmithKline noted that the article provided no evidence to support the headline 'Nurses earn bonuses for use of the latest drugs'. All of the information in the article related to nurses being incentivised according to the number of surgeries they attended or the number of patients or records they reviewed, and not the number of prescriptions dispensed for any particular medicine.

GlaxoSmithKline stated that it engaged nurses in patient review services across the following therapy areas to benefit health practitioners, patients and the NHS: asthma; chronic obstructive pulmonary disease (COPD); Diabetes; Osteoporosis; Parkinson's Disease and travel health.

GlaxoSmithKline was extremely confident that the patient review services that were carried out across all these areas complied with the Code and copies of the relevant documentation for all the review services

were provided. GlaxoSmithKline also provided details of the objectives and operation of each service.

GlaxoSmithKline submitted that its asthma patient review service was an appropriate example of the principles applied by it regarding the use of nurses in these programs and the compliance of these programs with the Code.

GlaxoSmithKline submitted that in any instance where particular therapeutic options might be discussed, information was presented on all other medicines within the class, and was not limited to medicines supplied by GlaxoSmithKline.

GlaxoSmithKline submitted that there were no individual key performance indicators for the travel medicine service that linked bonus levels to promotion, prescription or recommendation of any medicine.

GlaxoSmithKline noted that Clause 18.4 of the Code allowed for the provision of medical and educational goods and services which enhanced patient care, or benefited the NHS and maintained patient care, to be provided as long as such goods and services did not bear the name of any medicine and did not act as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine.

GlaxoSmithKline contended that its review and audit services complied with Clause 18.4 of the Code since it was clear from the protocols and agreements on which these services were strictly based that the services enhanced patient care in terms of identifying and reviewing appropriate patients as determined by pre-defined criteria and strict protocols agreed with clinicians prior to implementation of the services, and these services were not an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. The service agreements for all therapy areas set out which treatment recommendations clinicians would endorse according to the patient's current clinical regimen from a complete list of appropriate therapeutic options for those patients that included, but was not exclusive to, medicines supplied by GlaxoSmithKline. The services were not therefore an inducement to prescribe any particular medicine, or indeed solely GlaxoSmithKline medicines. In addition, the review service for Parkinson's Disease did not involve nurse advisors in presenting recommendations for, or alterations to, therapeutic, management of patients.

GlaxoSmithKline noted that The Sunday Times article stated: 'nurses are provided free to GP surgeries and are given access to patients' medical records to check whether they are on the most up-to-date drugs' and 'are earning bonuses of £3,500 by identifying NHS patients who can be put on costly new drug regimes'. GlaxoSmithKline submitted that whilst nurses were provided free to GP surgeries and given access to patients' medical records this was not in breach of Clause 18.4 since pharmaceutical companies were allowed to provide services that would enhance patient care or benefit the NHS, and GlaxoSmithKline's review and audit services would clearly deliver these benefits. In addition, whilst the nurses were given access to patients' medical records this was strictly controlled by health professionals

and, by seeking their signed consent to the search and the search criteria, allowed access to only those records of patients identified as being appropriate for review as agreed between the health professional and the nurse advisor. Furthermore, the nurse advisors were independent, and acted as a third party to ensure that no GlaxoSmithKline employees could access individual patient records.

GlaxoSmithKline submitted that it was clear from the details provided of its review and audit services that nurses were not given free access to patient records to 'check whether they are on the latest drugs'. The audit and review service protocols as agreed with the practice/clinic clearly set out the criteria for selection of patients that would be identified and reviewed through the services, and detailed the information that would be collected during the clinic reviews with the nurse advisor, which included personal history, medical history, clinical status and compliance in addition to current therapy. The nurse advisor, as a health professional, bound by a professional code of conduct, would only make treatment recommendations when the patient's current therapy was not consistent with their clinical status as required by the health professionals in the practice/clinic for that patient and as defined in the service agreements.

GlaxoSmithKline submitted that it was clear from the principles of remuneration of both individuals and the companies undertaking the review and audit services on behalf of GlaxoSmithKline that no scheme was in place to incentivise individuals for identifying patients that were suitable for new medicines. Indeed, the protocol in place as part of the review and audit services did not allow for the specific identification of patients that were suitable for new medicines, rather they identified patients that suffered from a particular condition as defined by criteria agreed with the health professional in the practice/clinic who could potentially benefit from a detailed review of their condition. During the review a number of factors were considered such as diagnosis, clinical condition, current therapy, compliance and side effects and, as a result of the review, a number of interventions might be considered, such as advice and education, as well as treatment changes. However, these changes were only recommended in accordance with the pre-defined protocols that had already been agreed with the practice/clinic.

With regard to The Sunday Times article, 'although they are barred from promoting their drugs firm's products, 15% of their pay is linked to the number of patients or records they see', 'nurse advisors are paid a salary of about £25,000 and usually a bonus of 10% to 15%', 'they [nurses] are rewarded for the number of surgeries that they visit' and 'it [agency] pays performance bonuses of up to £3,500', GlaxoSmithKline submitted that the nurse advisors involved in review and audit services were strictly prohibited from promotional activities and were subject to the Nursing & Midwifery Council (NMC) Code of Professional Conduct: standards for conduct, performance, and ethics as stated in the appropriate service authorisation agreements for each service. It

was not a breach of Clause 18.4 of the Code for these nurses to be incentivised according to the number of reviews they completed or the number of surgeries that they visited, since this did not constitute an inducement to prescribe, supply, administer, recommend, buy or sell any medicine and furthermore benefited both the NHS and the practices concerned for the review and audit services to be carried out as quickly and efficiently as possible.

GlaxoSmithKline submitted that the contracts it had in place for remuneration of nurse advisors under third party arrangements took account of a number of factors which were important in delivering these review and audit services, and in measuring the overall contribution of the review service to meeting the objectives of benefiting patients, practices and the NHS. It was important to note, however, that the actual numbers of patients identified for review and the treatment changes that were implemented as a result of services were driven solely by the criteria laid out in pre-specified agreements with practices and clinicians, and not by the activity levels of a nurse in an individual practice or clinic.

With regard to The Sunday Times article that 'nurses are routinely backed up by sales teams' GlaxoSmithKline submitted that it was difficult to understand exactly what was meant by this as it had sales representatives as well as review services, but actually what was meant by 'backed up' was unclear. However, the review and audit services did not breach Clause 18.4 of the Code since non-promotional activities were strictly separated from promotional activities. Although Clause 18.1 of the Code allowed for promotional representatives to introduce a review service, wherever possible this activity was separated further by using a strictly non-promotional representative team for this purpose. Where this had not been possible, activities of the promotional representatives were in accordance with the Code through a clear separation of promotional and non-promotional activities. Consequently, the review and audit services were either introduced by a non-promotional representative or a promotional representative during a strictly non-promotional call, and when agreement was received to proceed with the service the contact was passed to the non-promotional nurse advisor. In addition, GlaxoSmithKline had given recent guidance to all representatives and review service staff that during the period when the nurse advisor was undertaking a review service in a practice and for a period of two days either side of the review service taking place all promotional activity by the sales representatives was prohibited.

With regard to The Sunday Times article that 'nurses are described in promotional literature as being able to "influence" new prescriptions of their drug companies', GlaxoSmithKline submitted that without sight of the actual documents referred to it was difficult to know exactly what was being referred to. However, the review and audit services did not breach Clause 18.4 of the Code since nurse advisors were fully briefed on, and contracted to abide by, the strictly non-promotional nature of their roles and act according to the NMC Code of Professional Conduct.

A number of materials had been designed for the nurse advisors, none of which stated that there was an expectation for nurse advisors to influence new prescriptions for their medicines. For example the materials for non-promotional representatives introducing the asthma and COPD review services, stated that:

- the [agency] Nurse Advisors are “employed and managed by [the agency] and are completely independent of any pharmaceutical organisation; their independence is assured through the requirement to fulfil, at all times, the code of professional conduct as set out by the Nursing and Midwifery Council. This code governs their professional registration and states clearly that they must not use their registration to act in a promotional capacity”.
- this [patient review service] is a non-promotional service sponsored by Allen & Hanburys as a service to medicine.’

With regard to The Sunday Times article that the nurse ‘identifies patients with a specific condition’... ‘[it] opens the doors to a medical representative. They come in and close the business’, GlaxoSmithKline noted that these comments had been attributed to a recruitment consultant acting on behalf of the agency to recruit nurses to review services run by pharmaceutical companies. GlaxoSmithKline submitted that it had clear protocols in place for the conduct of the review and audit services which predefined the actions that would occur as a result of the individual patient reviews. The non-promotional nature of the review services was clearly separated from the promotional activity, with the prohibition of representative activity before, during and after the review service such that once patients with a specific condition had been identified all necessary actions, including treatment changes, were completed according to pre-defined protocols in agreement with the practice prior to any further representative activity. Accordingly it was not feasible that a nurse advisor could identify a patient such that any treatment change would be influenced by representative activity prior to the treatment change being introduced.

However, whilst both GlaxoSmithKline and the agency were very familiar with the details of the review services in place to enhance patient care and deliver benefits to the NHS it was possible that agents of its third parties such as recruitment consultants were not. As a result GlaxoSmithKline had requested that its third party agents reviewed their own arrangements for briefing their third party agents as to the details of, and the constraints of, the GlaxoSmithKline review services.

Consequently GlaxoSmithKline did not consider that its review and audit services were in breach of Clause 18.4 since they were very strictly set up to enhance patient care in line with the general requirements of the NHS and the specific requirements of individual practices or clinics and these services were not an inducement to prescribe, supply, administer, recommend, buy or sell any particular medicine. Furthermore, none of the comment in The Sunday

Times article was supported by protocols and contracts set with third party agents for the operation of these review and audit services.

GlaxoSmithKline noted that Clause 9.1 of the Code stated that high standards must be maintained at all times. GlaxoSmithKline submitted that it had endeavoured to set up beneficial services to patients and the NHS which took account of all aspects of the Code. The provision of review and audit services was based on informed consent to the service from practices or clinics and the establishment of a number of detailed agreements as to appropriate activities and actions for nurse advisors in accordance with health professional requirements and following detailed protocols and contracts. In addition, a practice satisfaction questionnaire had been incorporated as part of the review services to collate feedback from the NHS on their views of the review services. Consequently GlaxoSmithKline considered that high standards had been maintained at all times and therefore that there was no breach of Clause 9.1.

GlaxoSmithKline noted that Clause 2 of the Code stated that activities or materials associated with the promotion must never be such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry. GlaxoSmithKline considered that the highest standards had been maintained across all its review and audit services programs and that all activities and materials associated with the services were fully compliant with all aspects of the Code. Consequently GlaxoSmithKline submitted that there was no breach of Clause 2.

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.

The Panel noted that the documentation for the schemes offered by GlaxoSmithKline ensured that the practice agreed to the arrangements including identifying the search criteria, the inclusion and exclusion criteria to define patients appropriate for review and the treatment options from the full range of therapeutic options. Further each change of treatment had to be authorized and implemented by a GP and the reasons for changes documented.

The Panel considered that the roles of the GlaxoSmithKline promotional staff and non promotional staff appeared to be clearly separated. Where the representatives both promoted medicines and provided detailed information about the service it appeared that this was clearly separated in that the representatives could not carry out both functions at the same visit. This point was covered by the briefing material.

The Panel noted that the remuneration of the nurse advisors was linked to the number of patients seen, the number of clinics run and customer satisfaction; it was not linked to the prescription, supply, administration, recommendation or purchase of any medicine.

The asthma service was designed to enhance each practice's management of patients whose asthma was uncontrolled. There were three inclusion criteria, two of which referred to patients who were uncontrolled. The third referred to patients who were currently prescribed an inhaled corticosteroid and a long-acting beta-2 agonist in separate inhalers but did not state that such patients had to be uncontrolled. The exclusion criteria included patients with well controlled asthma. It was not clear whether a patient on two separate inhalers who was well controlled would be included in the audit. This should be clarified particularly as the section for the GP to sign to authorize the search did not include in the list of exclusion criteria 'patients with well controlled asthma'. This inconsistency in the documentation should be corrected. The Panel did not consider that the inconsistency meant that the material was in breach of the Code. There was an inhaler which combined a corticosteroid and a long-acting beta-2 agonist other than that produced by GlaxoSmithKline.

The Panel was curious as to why the osteoporosis service outlined details of 'Osteoporosis the disease' including the cost of fracture etc and advocated the use of effective treatments and lifestyle changes. None of the documentation for the other services included such a section. One of the objectives of the osteoporosis service was to improve practice knowledge of osteoporosis; the service reviewed patients currently on or previously prescribed treatment. The aim was to optimise the management of osteoporosis. The patient review protocol set out a list of actions for the nurse advisor to discuss with the patient. This included a discussion of treatment options. This was of concern given that the inclusion criteria were for patients currently prescribed medication for osteoporosis. There could be patients attending patient review who adhered to treatment and had no problems with side effects. Was it appropriate to discuss treatment options with such patients particularly given that Roche and GlaxoSmithKline had just introduced a once monthly treatment? The point would be covered by the treatment management plan agreed with the practice which should set out first line and second line interventions for lapsed patients (those previously prescribed treatment for osteoporosis), patients on repeat medication which appeared to be non adherent and those on repeat medication that appeared adherent. Patient preference was given as a reason for the therapy recommended as per the agreed treatment management plan.

The Representative Briefing Document for the osteoporosis service (dated November 2005) included an example of how the medical representative could initially introduce the service after a promotional call. The example referred to the health professional seeing the benefit offered by Bonviva and then asking whether the practice had an osteoporosis clinic. If the health professional said that there was not a clinic the representative went on to describe the unconditional nurse run service to medicine, to recall and review patients to help provide optimal care. The representative would offer for a colleague to discuss it further if wanted. The Panel had some concerns about this but did not consider this meant that the

introduction of the service was an inducement to prescribe, supply, administer, recommend or buy Bonviva. There was no implication that the health professional had to agree to use Bonviva before the service could be offered.

The diabetes service identified patients with diabetes, diabetes mellitus, type 2 diabetes, or non insulin dependent diabetes mellitus and stated that patients with an HbA_{1c} above a certain figure (determined by the practice) would be deemed as requiring additional control and would be reviewed by the practice.

The Parkinson's Disease service aimed to develop a Parkinson's Disease centre level clinical audit and review service by providing the resource to establish a clinical audit tool and process for each centre. All patients diagnosed with Parkinson's Disease would have their notes reviewed unless otherwise requested by the consultant. Patients requiring therapy would be flagged on the audit. These patients being all those who had not been reviewed within the last 12 months and all patients who required monitoring and medication review due to functionally limiting side effects. Patients were referred to the Parkinson's Disease nurse specialist at the centre and not the agency nurse advisor.

The main focus for the travel health service was to facilitate best practice and provide travel health advice and education to support health professionals in achieving the travel vaccination goals of the World Health Organisation. The service included the following components: patient search, vaccination clinic, education and materials provision. The objectives were to work with both GPs and practice nurses through education and audit to improve patient health status, patient and practice knowledge of travel related diseases and vaccination programmes and to provide practices with a comprehensive audit and review process. The Panel was unsure whether all the objectives would be met bearing in mind the overview and patient search related to booster Hepatitis A vaccination.

The objectives in the travel health service briefing material were given as 'Generating patient Hepatitis A booster vaccination opportunities', 'Proactively promoting good malaria management in line with recognised guidelines' and 'Developing practice nurse capability knowledge and confidence within the travel health arena'. The activity guidelines were 50% booster recall and 50% education. Travel health nurses would administer the booster vaccination which was supplied by the practice.

The Panel considered that some of the arrangements might be of concern as highlighted above. Much would depend on the practice which had control of every step of the process. Provided the nurse advisors complied with their professional codes, and there was no evidence that they had not, it did not appear to the Panel that the arrangements were in general necessarily unacceptable. There was no complaint about any specific arrangements, the complaints concerned the generality of the review services.

Overall the Panel considered that the services offered were not unacceptable; they would enhance patient

care. The provision of the services was not linked to the prescription of any specific medicine. The decision of what to prescribe lay with the patient's doctor. The Panel did not consider that the services were 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 Clauses 9.1 and 2 of the 2003 Code.

Case AUTH/1806/3/06

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