# THE SUNDAY TIMES/DIRECTOR and a GENERAL PRACTITIONER v PFIZER

## 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*, Pfizer. In accordance with established practice the matter was taken up by the Director as a complaint under the Code (Case AUTH/1807/3/06).**

**The article stated that Pfizer 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 Pfizer in providing nursing advisors as detailed in The Sunday Times (Case AUTH/1810/3/06). 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 Pfizer had sponsored nurses to enable a primary care trust (PCT) to perform a chronic obstructive pulmonary disease (COPD) audit. The provision of such nurses was not dependent upon the prescription of any Pfizer medicine. Any recommendations for management made by the nurse would be in accordance with the National Institute for Health and Clinical Excellence (NICE) COPD guidelines or from the relevant formulary. A draft protocol for the audit noted that four pharmaceutical companies would fund the work; the companies would have no involvement in the design of the audit or be able to influence its conduct. The Panel did not consider that the audit was an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of the Code was ruled.**

**With regard to a coronary heart disease (CHD) audit programme, the Panel noted that the agreement was to support a particular medical group with its project to implement nurse led CHD clinics. A document setting out the terms stated that for the avoidance of any doubt, the funding provided by Pfizer was a stand-alone arrangement and was not dependent on or related to any past, present or future commercial relationship with Pfizer nor any business decision that the practice might make relating to Pfizer or any of its products. The Panel thus did not consider that the audit was an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of the Code was ruled.**

**The Panel noted that a cardiovascular risk management programme was a national project provided by a team of nurse advisors. In a representatives' briefing the project was listed as one of four Lipitor value added programmes. Representatives were instructed that the first key consideration was to always sell Lipitor first and be confident that the practice supported the use of Lipitor in appropriate patients. The representatives should ensure that they had discussed, agreed and understood the practice patient management protocols and that these correctly positioned Lipitor as statin of choice for 'defined' patients groups. Representatives should understand how each of the value added programmes could support them and their customers. The representatives were reminded that the use of the programme should not be an inducement to prescribe and selected practices should continue to prescribe as they chose. A 2005 Outcomes Summary showed that in 109 completed practices, of 3,524 patients not treated to target, 2,756 (78%) were initiated or titrated on Lipitor. The summary slide informed representatives that targeting was critical so as to maximise benefit to them and their customer. Although the official contract between the practice and Pfizer contained the same statement as described above with regard to the nurse led CHD clinics, ie the funding provided by Pfizer was a stand-alone arrangement etc, the Panel nonetheless considered that the instructions to representatives, that the service should only be offered where they were confident that Lipitor would be used as the statin of choice in appropriate patients, were unacceptable. Similar instructions were included in the relevant service agreement between the nurse agency and Pfizer. The Panel thus ruled breaches of the Code including Clause 2.**

**The Panel noted that it had previously considered an outcomes guarantee study (Case AUTH/1109/11/00) wherein it had considered that the scheme, which at that time was a pilot study, was not in breach of the Code. The documents provided in respect of the case now at hand described an outcomes guarantee programme as being when a pharmaceutical company guaranteed that its medicine would achieve certain targets in a given patient group. The project aimed to ensure that those patients who would benefit from LDL cholesterol lowering medicines received them. Within the programme Pfizer had provided an outcomes guarantee for Lipitor although participating doctors were not obliged to prescribe it. Any rebate due under the terms of the guarantee was paid to a PCT for the general purpose of improving primary care services and not to individual general practices. The company submitted that this ensured that there was no financial inducement for prescribers to choose one**

**lipid-lowering medicine over another. It was stated that the programme and the support provided by Pfizer was not conditional upon or related to any commitment on the part of the PCT to purchase, prescribe, administer or recommend any Pfizer product. The Panel thus ruled no breach of the Code.**

**The COPD Response programme was also a nationally run project to identify primary care patients with COPD, or a component thereof, and ensure that they were optimally treated according to recognised national guidelines. Although representatives identified suitable practices the criteria they worked on did not include any reference to particular medicines. Pfizer hoped that provision of the service would foster closer relationships between the sales teams and the practices. There was, however, no obligation to use Pfizer products, although it was acknowledged that these were included in the national and European guidelines on the treatment of COPD. The Panel noted that the nurse advisor briefing document was for use by both the sales team and the nurse advisors. The selection of appropriate practices was by the sales team using a list of criteria, some or all of which were to be met. The criteria related to size, computerised notes, spirometer availability and an interest in respiratory medicine and COPD in particular. Sales representatives would attend the introductory meeting. The briefing document included objection handling. The response to maintenance of prescribing perogative was 'Whilst [a named pharmaceutical company] and Pfizer hope that you will consider the benefits of using their product for COPD patients there is no obligation to do so. The BTS COPD Guidelines and the European GOLD initiative both recommend treatment pathways that include [the named pharmaceutical company] products that are licensed for the management of COPD'. Overall the Panel did not consider that the COPD response programme was an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of the Code was ruled.**

**The Panel noted that Pfizer had provided some information about other similar programmes that it had run within the last three years. A standard letter relating to the payment of a nurse's overtime to allow her to conduct patient or medicine reviews stated that the funding provided by Pfizer was a stand-alone arrangement and was not dependent on or related to any past, present or future commercial relationship with Pfizer or any business or other decisions that the practice had or might make relating to Pfizer and its products. The Panel considered that the evidence before it was not such as to demonstrate that any of the programmes had been an inducement to prescribe, supply, administer, recommend or buy any medicine. No breach of the Code was ruled.**

An article entitled 'Nurses earn bonuses for use of latest drugs', which appeared in The Sunday Times on 3 March 2006, criticized the activities of, *inter alia*, Pfizer Limited. In accordance with established practice the matter was taken up by the Director as a complaint under the Code (Case AUTH/1807/3/06).

A general practitioner subsequently complained about the involvement of Pfizer in providing nursing advisors as detailed in The Sunday Times (Case AUTH/1810/3/06).

## COMPLAINT

The article stated that Pfizer 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 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 general practitioner 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 general practitioner that the story was correct. The general practitioner 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 considered halting any current nurse advisor activity until this case had completed.

When writing to Pfizer, the Authority asked it to respond in relation to Clauses 2, 9.1 and 18.4 of the Code and, if the activities had not taken place in 2006, to respond in relation to the requirements of Clauses 2, 9.1 and 18.1 of the 2003 Code.

## RESPONSE

Pfizer stated that it had ten programmes that it believed were relevant to this complaint. It had responded to this complaint on the basis of the 2003 Code, regardless of whether the programmes were current or not. In support of its submission, Pfizer provided the Authority with a large number of documents relating to the audit programmes.

With respect to the implied criticism of its nurse-led programmes in The Sunday Times article, Pfizer rejected the headline allegation that 'Nurses earn bonuses for use of latest drugs' and the implication that the objective of nurse-led programmes was to influence a switch of patients to 'costly new drug regimes'.

Pfizer's nurse-led primary care programmes benefited patients by giving them the time, attention and guidance which were not often available within the

average 7-minute GP consultation. This additional support helped GP practices improve the management of their patients' medical conditions in line with local and/or national NHS guidelines or targets.

The Sunday Times article alleged that 'there are no incentives to curb their [GPs'] drugs bills'. On the contrary, GPs were heavily incentivised locally and nationally to minimise their expenditure on medicines. It would not be in any practice's interest to participate in a programme that drove up costs without any economic or patient benefits.

GPs whose practices participated in Pfizer nurse programmes always retained freedom to choose which (if any) medicines to prescribe. Pfizer's medicines would not necessarily be chosen by participating practices and indeed, in some areas covered by these programmes, it did not make any of the relevant medicines.

Pfizer submitted that its nurse-led primary care programmes were ethical, legal, and complied with the Code and professional regulations. The benefit that Pfizer gained from these programmes was not a crude *quid pro quo*, whereby it provided a service in return for patients being switched to its medicines. Rather, by providing a specialist resource that might not otherwise be available, Pfizer supported GP practices in conducting a review of appropriate treatment in a particular patient population. Often this generated evidence that demonstrated the value of prescribing more effective medicines, in terms of reduced hospital admissions, fewer repeat patient visits, a reduction in complications arising from under-treatment, and therefore lower overall costs to the NHS. Clearly, where these more effective medicines were Pfizer medicines, there was a commercial benefit for the company.

Pfizer did not accept that this potential benefit rendered these programmes unacceptable – rather it represented an advantage for the NHS, for patients and for Pfizer. It was important to note that there was no direct or guaranteed return to Pfizer from these programmes.

The process by, and purpose for, which the nurse advisors were placed in GP practices was explained below in relation to each programme. In each case, access to patients' records was granted by GPs in order to see whether patients were being treated in accordance with relevant local and national prescribing guidance. Although recommendations might be given by nurse advisors (on the basis of the local or national NHS guidelines or targets or the practice's protocol), prescribing decisions were made by a GP.

The Sunday Times article also highlighted the number of nurses, the fact that their wages were effectively paid by pharmaceutical companies and certain bonus arrangements which were alleged to be linked to the number of patients or records that the nurses saw or the number of surgeries that they visited or the switch to 'costly new drug regimes' and thus act as an inappropriate incentive.

Pfizer submitted that the fundamental question was whether the nurses' activities were appropriate: if so, the number of nurses or the arrangements under which they were paid or incentivised was irrelevant. However, for the sake of completeness Pfizer's current programmes involved 14 nurse advisors. So far as it was aware, any bonuses paid under the programmes were based on legitimate criteria and did not exceed 10% of salary. The detail of any applicable bonus arrangements in relation to each individual programme was explained below. None of the programmes had a bonus scheme that was based on the number of patients or records seen or surgeries visited, the switch to costly new drug regimes or the sales or promotion of any product.

**Specific issues relating to current programmes**

1 Nurse Agency Primary Care COPD Audit – a local PCT

Pfizer submitted that it had funded a COPD programme together with a number of other pharmaceutical companies. Pfizer's involvement related to the hire of one full time equivalent nurse advisor and one project administrator from a nurse sales agency. The arrangement expired on 31 March.

As this was a very limited programme, the best documentation that Pfizer had to describe it was the related legal contract. The aim of the programme was, *inter alia*, to 'ensure optimal control of diagnosed, treated COPD patients in accordance with NICE and/or local guidelines'. Pfizer co-promoted Spiriva (tiotropium bromide) with another pharmaceutical company; the product was licensed for the treatment of COPD. The contract stated that:

> 'The Nurse's role is to provide a professional and ethical COPD review programme to Pfizer customers at Primary Care level. This COPD audit will assess the standards of care of approximately 2,500 COPD patients in general practices. The data will be used to quantify the effectiveness of current treatment and management protocols and highlight the areas requiring investment, development and improvement.'

The standard operating procedure to the contract made clear the sort of report that was produced for patients by the agency nurse. Attention was drawn particularly to the points highlighted below in italics:

'For the patient, the report will indicate disease severity from spirometry, *according to NICE guidelines*, their exacerbation status, their smoking status, and their questionnaire scores. Information leaflets will be provided as indicated by the LINQ scores. The report will also include *recommendations for management according to NICE COPD guidelines and from the relevant Formulary.* The recommendations will include:

> Drug treatment
> Non-drug management
> Referrals e.g. smoking cessation, pulmonary rehabilitation
> Suggested follow-up GP/practice nurse

This report will be reviewed by the Nurse who will be able to make appropriate modifications before giving

it to the patient. This report will not give specific details of drugs just that their treatment regime may need reconsidering in the light of current guidelines and requires further discussion with their GP.'

Pfizer submitted that this programme was not prohibited by Clause 18.1 of the Code. As required by the supplementary information to Clause 18.1 of the Code, Pfizer ensured that:

- The programme was delivered by an appropriately qualified nurse and a GP made the decision about whether and, if so, how to change the patients' treatment. Although the contract referred to the GP getting a report 'detailing the treatment recommendations', this clearly only referred to *recommendations* – it was up to the GP to decide whether to modify the patients' treatment.
- Pfizer avoided access to data/records that could identify particular patients.
- The remuneration of the agency staff was not linked to sales in any way. There were no bonus payments associated with this arrangement (see contract for the payment terms).
- Patient confidentiality was maintained and data protection laws complied with.
- A written protocol was provided for the recipients of the programme, which outlined the services to be provided and the role of the sponsoring pharmaceutical companies.

Pfizer also required that the agency staff (including the nurse):

- received proper training in respect of the Code, as amended from time to time; and
- complied with all applicable laws, codes, regulations including the Code and the Nursing & Midwifery Council (NMC) Code.

As recommended by the Code, Pfizer had also ensured that relevant parties were informed of the activities.

2 Nurse Agency Audit Programme in Coronary Heart Disease

Pfizer's programme was put in place in response to a request from the local PCTs in relation to their CHD management programme. This arrangement involved the hire of one nurse advisor and project administrator from the agency. The contract between Pfizer and a nurse agency stated that the aim of the programme was to 'identify, review and treat patients with long term conditions'. The support was to enable 'practices to deliver a high standard of care to patients with cardiovascular disease, and deliver recommendations from the National Service Framework for Coronary Heart Disease and British Hypertension Society Guidelines'.

The contract made clear the sort of report that was produced for the patient and the patient's GP. Attention was drawn particularly to the points highlighted in italics:

> '…patients will be given a treatment card where all advice and treatment that has been given in the clinic will be recorded…. The report to the Practice will also include recommendations for management *according to NICE CHD guidelines and from the relevant Formulary.* This report will be reviewed by the Nurse who will be able to make appropriate modifications before giving it to the patient. The recommendations will include:
>
> Non-drug management
> *Referrals* e.g. smoking cessation, cardiac rehabilitation; and exercise counselling
> Suggested follow-up GP/practices' nurse.
>
> This report *will not give specific details of drugs or treatments.* It may state that a patient's treatment regime may need reconsidering in the light of *current guidelines* and/or requires further discussion with their GP.'

The contract also set out strict parameters for the circumstances in which the patient's further management would be discussed with the GP:

- 'patients whose assessment indicated active exacerbation of disease who might benefit from a change in therapy
- patients whose assessment indicated symptom recurrence due to inappropriate preparation or form of medication
- patients with symptoms that warranted further investigations at secondary care level
- patients experiencing chest pain during clinic would be managed according to local protocols'.

Pfizer submitted that this programme was not prohibited by Clause 18.1 of the Code. As required by the supplementary information to Clause 18.1, Pfizer had ensured that:

- The audit services were delivered by an appropriately qualified nurse.
- The remuneration of the agency staff was not linked to sales in any way. There were no bonus payments associated with this arrangement.
- Patient confidentiality was maintained and data protection laws complied with.
- The recipients of the service (two GP practices) each had a written agreement for the arrangements, describing the services to be provided and Pfizer's role. The contracts with the GP practices made it clear that the arrangements were not dependent on or related to 'any business or other decision(s) that the practice had made or might make relating to Pfizer or any of its products'.
- As recommended by the Code, relevant parties were informed of the activities.

Pfizer also required that the agency staff (including the nurse):

- complied with all applicable laws, codes, regulations including the ABPI Code and the NMC Code of Professional Conduct; and
- provided the services only in accordance with the protocol agreed by the Trust and any relevant practices.

3 Nurse Agency Advisor Programme relating to Cardiovascular Risk Management

Pfizer submitted that the best description of this programme was provided by the two short booklets entitled 'Cardiovascular Risk Management programme' and '[a nurse agency] Cardiovascular Risk Management programme'. This programme involved 12 nurse advisors and was designed to support primary care practices in identifying and ensuring optimal management of patients with cardiovascular disease and diabetes by assessing cardiovascular risk and providing treatment recommendations in accordance with national and local guidelines. The programme re-assessed and reviewed patients with a history of CHD, diabetes, hypertension and stroke and captured practice information to meet the GMS quality and outcomes framework that GP practices were required to report on. The aims of the programme included 'to ensure patients with diagnosed CVD and diabetes achieve optimal management including cholesterol targets *in accordance with GMS and/or local guidelines*' and 'to help customers maximise GMS points in the field of CHD, stroke/TIA, hypertension and diabetes'.

Although the programme focused on the prescription of statins (which could include Lipitor), it also tested for medical conditions and carried out medical interventions that had no relevance to any medicines made by Pfizer (eg influenza inoculations). One of the slides provided showed the broad extent of the matters covered in clinics run under this programme.

Practices interested in entering the programme were identified by Pfizer's sales representatives and checked against certain listed criteria (including the practice having an interest and commitment to running statin management and CHD clinics, an agreed cholesterol and statin treatment protocol and being fully computerised – all these elements were necessary in order for the programme to work). Assuming that the practice met the criteria, Pfizer's District Leadership Team had to agree to the practice joining the programme, to ensure that the number of practices joining did not overstretch or exceed the available resource.

If the practice proceeded with the programme, Pfizer's sales representative would ensure that one of the GPs: (a) documented the practice's agreed cholesterol and statin treatment protocol on Pfizer's standard form 'Cardiovascular Risk Management and Review Protocol' and (b) completed a standard 'Referral Form'. The standard Protocol and Referral forms, together with some completed examples which showed the wide variation between different practices' protocols and the fact that not all completed protocols would favour Pfizer's medicine Lipitor, were provided. These forms were sent to the agency where they triggered the scheduling of a meeting between the nurse advisor and the practice (as described in the booklet under 'Initial Meeting') at which the nurse reconfirmed and/or clarified the work that the practice wished her to carry out. The nurse advisor then had to sign a contract with the practice, committing to confidentiality obligations so that she could access the practice's data and implement the Cardiovascular Risk Management and Review Protocol chosen by that practice.

Further details of the practical process involved in the referral and the various stages of the agency nurse advisor's role in the programme were explained in the '[Agency] Standard Operating Procedure Pfizer Cardiovascular Risk Management Programme' document. If the practice wished to proceed with the programme, a formal contract between Pfizer and the practice had to be signed.

Broadly speaking, the programme provided a screening service for patient groups identified via a record search, in accordance with the practice's requirements. Patients were sent an appointment to attend a clinic at which they received relevant screening according to the request of the practice and the target disease area. This might include assessment of BP, cholesterol, BMI, urinalysis, diabetic neuropathy assessment and random glucose. Nurses also provided lifestyle guidance, for example about the importance of exercise and diet.

If, following this assessment, the patient met any criteria for further management he/she would either be seen by, or have his/her case reviewed by the GP who would make any decision about the future management of the patient's health.

Pfizer submitted that this programme was not prohibited by Clause 18.1 of the Code. As required by the supplementary information to Clause 18.1, Pfizer had ensured that:

- The programme was delivered by an appropriately qualified nurse – the contract required the agency to ensure that the nurse advisors were appropriately qualified. In addition the '[Agency] Protocol of Confidentiality for an [Agency] Nurse Advisor Working in General Practice' confirmed that all agency nurse advisors were NMC registered.
- A GP decided whether and, if so, how to change the patients' treatment (by completing the 'Cardiovascular Risk Management and Review Protocol' and confirming or changing it during the initial meeting). In the '[Agency] Cardiovascular Risk Management programme' under the heading 'Can I feel confident in an Industry-sponsored programme?', it was clearly stated that 'all prescribing choices are made by the practice'. Similarly, the patient brochure stated 'if medical treatment is advisable for you, the Nurse Advisor will discuss this with your doctor and any treatment your doctor recommends will be explained to you'.
- Pfizer had no access to data/records that could identify particular patients. The sales representatives' involvement ceased before the initial meeting (ie before there was any access to patient data). The '[Agency] Protocol of Confidentiality for an [Agency] Nurse Advisor Working in General Practice' committed the nurse advisors to adhere to the Caldicott Principles of Good Practice and included assurances that:
  - the nurse advisors were NMC registered and therefore governed by the Code of Professional Conduct and Scope of Professional Practice;
  - no access to patient records could be sought by the nurse advisors unless they had the signed agreement of the patient or GP;

- all patient information would be coded: no identifiable patient information would be removed from practices (all 'keys' to patient data would be held at the practice); and
- any information given to Pfizer would be coded, anonymised and aggregated.

- Patient confidentiality was maintained and data protection laws complied with. The contract provided that '[Agency] will ensure the confidentiality of patients' medical records at all times and shall not share such records with Pfizer'. One whole clause of the contract was devoted to data protection obligations. In addition to the points made above, the '[Agency] Protocol of Confidentiality for an Agency Nurse Advisor Working in General Practice' also contained assurances that:
  - the nurse advisors complied with the Data Protection Act (relevant extracts from the Act and example patient consent forms were also provided); and
  - in addition to being bound by the NMC Code of conduct, the nurse advisors would ensure that patient data would be anonymised and, where necessary, patient consent obtained.
- The Agency Cardiovascular Risk Management Programme explained this programme to the recipient practices and this clearly identified both the service provider and Pfizer's role eg the section entitled 'Can I feel confident about an Industry-sponsored programme?'. In addition, the contract referred to the need for each participating practice to sign a letter in the form specified in the contract. The printed materials designed for use in connection with the programme were non-promotional and clearly identified Pfizer as the sponsoring company. None of the materials criticised competitor products.

Pfizer also required that:

- the agency nurses received proper training in respect of the ABPI Code, as amended from time to time; and
- all agency staff involved in delivering the programme complied with all applicable laws, codes, regulations including the ABPI Code and the NMC Code.

Pfizer submitted that because of the size of this programme, its sales representatives were specially briefed about it. The slides used made it clear to the field force that the programme should not be used as an inducement to prescribe and that practices should continue to prescribe as they saw fit.

In response to a request for further information Pfizer noted that the relevant briefing material contained the following guidance:

> 'In accordance with Clause 18.1 ABPI Code of Practice the Nurse Advisor programme must not be linked to the sales call. There must be a clear separation between the promotion of product/sales call and any discussion with practice personnel around offering the Nurse Advisor programme to assist with a surgery therapy review.'

To help maintain this separation and to enable each practice to evaluate the service in the absence of a representative, a general guide to the service was left with practices which stated 'the service is non-promotional – all prescribing choices are made by the Practice'.

In addition, the slides used to brief the representatives on this programme included one which set out 'ABPI Considerations'. This slide made it clear to the field force that the programme should not be used as an inducement to prescribe and that practices should continue to prescribe as they see fit.

Bonus payments

Pfizer explained that bonus payments might be earned by nurse advisors under this programme, but the remuneration was not linked to sales or promotion.

The nurse advisors' salary and bonus changed between 2005 and 2006. Pfizer provided details.

According to the agency documentation, from January to June 2006 this bonus was awarded on the basis of:

- completion of more than 2.5 audits per month (Pfizer noted that as nurse advisors could only visit a practice after it had been referred and had agreed to the initial meeting, this element of the bonus related to the efficiency of each audit, rather than to gaining access to additional practices);
- drive for patient attendance at clinics (to improve patient outcomes);
- communication, client and customer feedback (including feedback from the practices); and
- reporting/administration (25% of bonus might be lost for late or inaccurate reporting).

Before 30 January 2006 the bonus was awarded on the basis of four equally weighted 'key areas' briefly described as:

- timeliness in carrying out practice audits;
- reporting/administration;
- communication with client and customer; and
- value added services eg training and supporting colleagues.

**Specific issues for programmes involving an agency and/or recruitment consultancy within the last three years**

Pfizer submitted that it had not run any nurse advisor audit programmes through the recruitment consultant but it had had two programmes with the agency in the last three years and these were detailed below.

4 Nurse Agency Assistance with Outcomes Guarantee programme

Pfizer stated that this programme had ended in June 2005.

The Outcomes Guarantee programme differed significantly from the other nurse programmes described above, due to its reimbursement (or 'guarantee') element. The Outcomes Guarantee programme was the subject of an earlier complaint to

the Authority [Case AUTH/1109/11/00]; the Panel had ruled no breach of the Code.

The Outcomes Guarantee Project Summary (LIP 374) described the programme as follows:

> 'An Outcomes Guarantee programme is when a pharmaceutical company guarantees that its drug will achieve certain targets in a given patient group. If the drug does not reach these targets then the company will reimburse the healthcare team for the shortfall between the target and what the drug actually achieved. In this programme, Pfizer Ltd has provided an Outcomes Guarantee for its cholesterol-lowering drug, atorvastatin. A doctor who participates in this programme is under no obligation to prescribe the drug involved in the Outcomes Guarantee programme.'

The agency had provided nurse advisors to help implement the Outcomes Guarantee programme by assisting the PCTs in 'identifying through general practice audit those patients who were most at risk from cardiovascular disease, including patients with diabetes'.

Pfizer submitted that this programme was not prohibited by Clause 18.1 of the Code. As required by the supplementary information to Clause 18.1, Pfizer had ensured that:

- The programme was delivered by appropriately trained nurses and the GP decided which statin to prescribe.
- The support provided by Pfizer was a service to the NHS and the wider community and was 'not conditional upon nor related to any commitment on the part of the PCT to purchase, prescribe, administer or recommend any products of Pfizer'. In addition, in order to ensure that there were no financial inducements for prescribers to choose one lipid-lowering agent over another, 'any rebates due under the terms of the guarantee was paid to the PCT for the general purpose of improving primary care services and not to individual general practices'.
- Pfizer avoided access to data/records that could identify particular patients.
- The remuneration of the nurses was not linked to sales. There were no bonus payments associated with this arrangement.
- Patient confidentiality was maintained and data protection laws complied with.
- The recipients of the service were required to enter into a written agreement with Pfizer, which described the programme and Pfizer's role.
- As recommended by the Code, relevant parties were informed of the activities.

Pfizer also drew attention to the following:

- The programme was approved by the local Scientific Merit and Ethics Committee. Approval was only granted once the Committee 'had established that there was no directive to prescribe a particular lipid-lowering agent'.
- The agency was required to ensure that its personnel were familiar with and complied with the Code.
- The agency staff involved in delivering the programme were obliged to comply with the NMC Code.

5 Nurse Agency Advisor Programme relating to COPD

Pfizer submitted that this programme was sponsored by another pharmaceutical company for a considerable period of time before it became involved in it. The contract setting out Pfizer's involvement in the programme ran from January to June 2003. The programme involved the sponsorship of 40 nurses, four field managers, two team administrators and one project director from the agency to carry out the 'COPD Response Programme'.

The best description of the programme was provided by the booklets entitled 'COPD Response' and 'COPD Response Nurse Adviser Programme Briefing Document', which were provided by the sales representatives and the agency team. The programme was designed to provide COPD education and support to primary care teams with the aim of improving diagnosis, management and treatment of COPD. Because of the size of the programme, sales representatives were specially briefed about it and liaised with the agency nurses to select suitable practices, introduce the nurse and the programme to the practice and discuss the progress of the programme. The contract (which was provided) comprehensively described the programme the objectives of which were:

'To identify primary care patients with COPD or a component thereof leading to optimal therapeutic management according to recognised guidelines (British Thoracic Society/GOLD). A crucial element of the programme was the transfer of skills from the nurse to the practice. The programme is structured to allow the practice nurse to develop the necessary skills and confidence to continue to identify patients once the nurse has completed the clinic cycle in this document.'

Practices suitable for the programme were identified by representatives and checked against certain listed criteria. These included the practice having an interest in respiratory medicine and COPD in particular, its own or regular access to a spirometer, and computerised patient notes (all these elements were necessary in order for the programme to work) as well as being of a sufficient size to ensure that limited resources were used sensibly.

If the practices were interested in the programme, approval would be sought from Pfizer's district sales managers to ensure that the number of practices joining the programme did not overstretch or exceed the resource available for it and that the representative had correctly applied the criteria. In some cases the representative would attend an introductory meeting with the practice to introduce the nurse and the programme to the key decision makers in the practice. The representative would not promote any product at this meeting. At the introductory meeting the practice would sign a 'Practice Agreement' which confirmed that this programme was not conditional upon or related to any commitment on the practice's part to prescribe,

administer, purchase or recommend any particular product, and that patient confidentiality would be maintained at all times.

Once a practice had signed up to the programme, the patients were selected for clinical review on the basis of their respiratory history, smoking history, occupation, and whether they had had more than two antibiotic prescriptions for an upper or lower respiratory tract infection in the previous six months. Patients meeting the criteria would then be invited for clinical review with the COPD nurse and the practice nurse. If, following this assessment, the patient met any criteria for further management the patient would be referred to the GP who would make any decision about the future management of the patient's health. The agency nurse also provided an education workshop for the practice, monitored the programme and provided support to the practice nurse for a limited period once the programme was complete.

Pfizer submitted that this programme was not prohibited by Clause 18.1 of the Code. As required by the supplementary information to Clause 18.1 of the Code, Pfizer ensured that:

- The programme was delivered by appropriately qualified nurses as the contract required the agency to ensure that the nurse advisors were appropriately qualified and experienced.
- A GP made all prescribing decisions in relation to a patient's treatment, following the review by the nurse.
- Pfizer had no access to data/records that could identify particular patients.
- Patient confidentiality was maintained. The contract provided that '[the agency] shall ensure at all times that the confidentiality of patients' medical records were maintained, and the agency would not share such records with the companies'.
- The contract made it clear under the heading 'Roles and Responsibilities' that sales representatives 'must not promote Spiriva, in meetings arranged to discuss the Programme'; that the agency nurses 'will not promote any specific products (including Spiriva)', and that the work of the nurses 'does not entail any prescribing obligations on the part of the practice'.
- A whole clause of the contract was devoted to data protection obligations, including obligations to:
  - comply with the Data Protection Act; and
  - only process personal data in accordance with the approval of the relevant GP, the Act, the Code and for no other purpose than the necessary administration of the services agreed in the contract.
- The recipient of the service would have a written agreement of the arrangements explaining the service and Pfizer's role. The contract referred to the need for each participating practice to sign a letter.

Pfizer also required that:

- The nurses received proper training in respect of the Code, as amended from time to time; and
- The agency ensured that the nurses performed the services in compliance with all applicable laws, codes, regulations including the Code and the NMC Code of Professional Conduct.

The agency was paid a daily fee for each nurse working on the programme; details were provided. Elements that were included within the fee included national insurance contributions, sick pay, maternity pay, pension, vehicle costs and a daily allowance.

Bonus payments

An annual average nurse bonus payment was included in the fee paid to the agency. Neither this bonus nor the remuneration of the nurses or agency was linked to sales or promotion. Nurses were rewarded for meeting certain project-specific objectives which could be briefly described as: timely completion of audits; customer satisfaction and the revenue generated for the agency from Pfizer under the contract.

**Other similar programmes within the last three years**

Pfizer had conducted a number of programmes which had completed within the last three years, which were listed below.

- A six month nurse advisor programme with an agency relating to COPD which aimed to: accelerate the rate at which COPD patients were reviewed through patient clinics; transfer skills to nurses and enable ongoing review of patients and ensure optimal control of diagnosed, treated COPD patients in accordance with NICE and/or local guidelines.
- A six month nurse advisor programme with the agency which supported the implementation of the PCT statin guidelines in GP practices in relation to 'at risk' patients, as identified by the PCT.
- A nurse advisor programme with the agency relating to cholesterol management of patients at risk of coronary heart disease, which was the precursor to, and ran on similar lines to, programme 3 above.
- Various nurse advisor programmes with a nurse agency whereby the agency personnel reviewed primary care patients through COPD and CHD clinics, carried out system searches for practices and provided IT, spirometry and CPR training to practice staff. None of these programmes was ongoing but Pfizer provided for completeness a copy of the standard contract used with the agency.
- An osteoarthritis/rheumatoid arthritis patient review service with a nurse and IT consulting agency which ran from November 2002 to September 2003.
- Pfizer sometimes paid the costs of a practice nurse's overtime to allow her to conduct patient or medicines reviews as required by the practice.

Such payments were made directly to the GP practice concerned. Since no agency was involved, it considered that these arrangements fell outside the scope of this complaint but it had provided for completeness a copy of the standard form contract used in these circumstances.

### Other issues

Pfizer submitted that it should be evident from the above that it and the agencies with which it worked had taken care to ensure that nurse programmes were run appropriately. In addition to the documentation relating to the programmes mentioned above, Pfizer provided various procedures, guidance and template agreements it had issued in order to ensure that its activities were properly run. The materials relating to the nurse programmes described above were approved in accordance with Pfizer's procedures, established to ensure compliance with the Code as well as with the law and Pfizer's own internal requirements. The nature and extent of the safeguards put in place demonstrated the lengths to which Pfizer had gone to ensure that its nurse programmes were run in an ethical manner and in compliance with legal and Code requirements.

### Conclusion

Pfizer submitted that none of its programmes breached Clauses 18.1, 9.1 or 2 of the Code.

## PANEL RULING

The Panel noted that some of the services were used in 2006. The article had appeared and the complaint had been received in March 2006. However the transition period for the 2006 Code stated that during the period 1 January 2006 to 30 April 2006 no promotional material or activity would be regarded as being in breach of the Code if it failed to comply with newly introduced requirements. Clause 18.4 of the 2006 Code was a newly introduced requirement. Most of the supplementary information to Clause 18.4 had been in the 2003 Code as supplementary information to Clause 18.1. These cases were considered in relation to the 2003 Code using the 2006 Constitution and Procedure.

Medical and educational goods and services had to enhance patient care or benefit the NHS under the supplementary information to Clause 18.1 of the 2003 Code. The change under Clause 18.4 of the 2006 Code was that such services had to either enhance patient care or benefit the NHS and maintain patient care.

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 results 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 sponsored health professionals should not be involved in the promotion of specific products. Nurses were required to comply with the Nursing & 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 Pfizer had sponsored nurses at a PCT to perform a COPD audit. The provision of such nurses was not dependent upon the prescription of any Pfizer medicine. Any recommendations for management made by the nurse would be in accordance with NICE COPD guidelines or from the relevant formulary. A draft protocol for the audit noted that four pharmaceutical companies would fund the work; the companies would have no involvement in the design of the audit or be able to influence its conduct. The Panel did not consider that the audit 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 Clauses 9.1 and 2 of the 2003 Code.

With regard to the CHD audit programme, the Panel noted that the agreement was to support a particular medical group with its project to implement nurse led CHD clinics. A document setting out the terms stated that for the avoidance of any doubt, the funding provided by Pfizer was a stand-alone arrangement and was not dependent on or related to any past, present or future commercial relationship with Pfizer nor any business decision that the practice might make relating to Pfizer or any of its products. The Panel thus did not consider that the audit 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 Clauses 9.1 and 2 of the 2003 Code.

The Panel noted that the cardiovascular risk management programme was a national project provided by a team of nurse advisors. In a briefing to representatives the project was listed as one of four

Lipitor value added programmes. Representatives were instructed that the first key consideration was to always sell Lipitor first and be confident that the practice supported the use of Lipitor in appropriate patients. The representatives should ensure that they had discussed, agreed and understood the practice patient management protocols and that this correctly positioned Lipitor as statin of choice for 'defined' patients groups. Representatives should understand how each of the value added programmes could support them and their customers. The briefing to representatives included a reminder that the use of the programme should not be an inducement to prescribe and selected practices should continue to prescribe as they chose. A 2005 Outcomes Summary showed that in 109 completed practices, of 3,524 patients not treated to target, 2,756 (78%) were initiated or titrated on Lipitor. The summary slide informed representatives that targeting was critical so as to maximise benefit to them and their customer. Although the official contract between the practice and Pfizer contained the same statement as described above with regard to the nurse led CHD clinics, ie the funding provided by Pfizer was a stand-alone arrangement etc, the Panel nonetheless considered that the instructions to representatives that the service should only be offered to those practices where a representative was confident that Lipitor would be used as the statin of choice in appropriate patients were unacceptable. Similar instructions were included in the relevant service agreement between the agency and Pfizer. The Panel thus ruled a breach of Clause 18.1 of the 2003 Code. The Panel further ruled breaches of Clauses 2 and 9.1.

The Panel noted that it had previously considered the outcomes guarantee study (Case AUTH/1109/11/00) wherein it had considered that the scheme, which at that time was a pilot study, was not in breach of Clause 18.1 of the Code. The documents provided in respect of the case now at hand described an outcomes guarantee programme as being when a pharmaceutical company guarantees that its medicine will achieve certain targets in a given patient group. The project aimed to ensure that those patients who would benefit from LDL cholesterol lowering medicines received them. Within the programme Pfizer had provided an outcomes guarantee for Lipitor although a doctor participating in the project was not obliged to prescribe it. Any rebate due under the terms of the guarantee was paid to a PCT for the general purpose of improving primary care services and not to individual general practices. The company submitted that this was to ensure that there was no financial inducement for prescribers to choose one lipid-lowering medicine over another. It was stated that the programme and the support provided by Pfizer was not conditional upon or related to any commitment on the part of the PCT to purchase, prescribe, administer or recommend any Pfizer product. The Panel thus ruled no breach of Clause 18.1 of the 2003 Code. The Panel also ruled no breach of Clauses 2 and 9.1 of the 2003 Code.

The COPD Response programme was also a nationally run project to identify primary care patients with COPD, or a component thereof, and ensure that they were optimally treated according to recognised national guidelines. Although representatives identified suitable practices the criteria they worked on did not include any reference to particular medicines. Pfizer hoped that provision of the service would foster closer relationships between the sales teams and the practices. There was, however, no obligation to use Pfizer products although it was acknowledged that these were included in the national and European guidelines on the treatment of COPD. The Panel noted that the nurse adviser briefing document was for use by both the sales team and the nurse advisers. The selection of appropriate practices was by the sales team using a list of criteria, some or all of which were to be met. The criteria related to size, computerised notes, spirometer availability and an interest in respiratory medicine and COPD in particular. Sales representatives would attend the introductory meeting. The briefing document included objection handling. The response to maintenance of prescribing perogative was 'Whilst [a named pharmaceutical company] and Pfizer hope that you will consider the benefits of using their product for COPD patients there is no obligation to do so. The BTS COPD Guidelines and the European GOLD initiative both recommend treatment pathways that include [the named pharmaceutical company] products that are licensed for the management of COPD'. Overall the Panel did not consider that the COPD response programme 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 Clauses 9.1 and 2 of the 2003 Code.

The Panel noted that Pfizer had provided information about other similar programmes that it had run within the last three years. A standard letter relating to the payment of a nurse's overtime to allow her to conduct patient or medicine reviews stated that the funding provided by Pfizer was a stand-alone arrangement and was not dependent on or related to any past, present or future commercial relationship with Pfizer or any business or other decisions that the practice had or might make relating to Pfizer and its products. The Panel considered that the evidence before it was not such as to demonstrate that any of the programmes had been 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/1807/3/06**

**Proceedings commenced** **10 March 2006**

**Case completed** **3 July 2006**

**Case AUTH/1810/3/06**

**Complaint received** **13 March 2006**

**Case completed** **3 July 2006**

**CASE AUTH/1814/3/06**

# FORMER EMPLOYEE v MERCK SHARP & DOHME

## Nurse audit programme

**A former sales representative, writing under a pseudonym, complained about a nurse audit disease management programme offered by Merck Sharp & Dohme and delivered by a service provider. The complainant referred to this as the Hypertension Review Programme Supportive of the GMS Contract (HRP-GMS).**

**The complainant stated that the HRP-GMS programme had been in operation from 2004 to the present day. Throughout this time, Merck Sharp & Dohme's representatives involved in the first-line promotion of Cozaar (losartan) had been given primary responsibility for identifying surgeries that were to be offered nurse advisors from the service provider to undertake audits relating to hypertension and Type 2 diabetes. The stated goals of the HRP-GMS were to improve patient management and support practices to achieve GMS contract targets in these disease areas.**

**The complainant was concerned about the way in which representatives and their managers had to select surgeries to be considered for placement of a nurse advisor. In this regard the complainant noted that the hypertension and Type 2 diabetes proformas explicitly referred to a number of sales and prescribing behaviour metrics to be fulfilled before a particular surgery was offered the service. The complainant understood that this was in breach of the Code as services to medicine and product promotion must not be linked in any way. An email from a senior manager in the Cozaar team, and a slide presentation entitled 'COZAAR Nurse Audit Programme', showed that representatives and their managers were required to complete the proformas in order to secure placements.**

**The complainant stated that he had raised his concerns with several superiors within Merck Sharp & Dohme but repeatedly failed to receive a substantive answer to questions.**

**The complainant also alleged that Merck Sharp & Dohme representatives were set annual objectives which required them to call on target doctors up to six times within a six month period. The complainant and other colleagues raised this issue with line managers to be told that call frequency must be elevated during a launch phase and that representatives must use their acumen to circumvent the restrictions imposed by the Code.**

**The Panel noted Merck Sharp & Dohme's submission that there were differences between the slides sent by the complainant and the Cozaar nurse audit programme briefing slides used by the company to train the representatives. The Panel noted that the training slides, as provided by Merck Sharp & Dohme, were branded with the Cozaar logo. The first slide referred to the 'COZAAR Nurse Audit Programme'. The service would thus be seen by representatives as being linked to the promotion of the product. No mention was made in the presentation of the need to separate the provision of medical and educational goods and services from the promotion of medicines. This was totally unacceptable.**

**The slides provided by Merck Sharp & Dohme included instructions that the audit service was only to be offered to practices that, *inter alia*, had 'Strong buy into LIFE and COZAAR messages'. Surgeries had to agree to Cozaar as the medicine of choice in relation to 'A' as set out in the British Hypertension Society (BHS) guidelines where A meant ACE inhibitor or angiotension antagonist. The practice also had to have a 'call rate of 6 prior to audit plus speaker meeting attendance'. The surgeries selected must have target doctors as project lead. The programme was referred to as a targeted resource to influence the environment.**

**The aim of the programme was to provide practices with an independent nurse advisor to review all uncontrolled hypertensive patients over 55 in order to improve blood pressure management in accordance with the ABCD goal (this was taken to be a reference to the BHS guidelines). The programme aims included the benefits of restoring blood pressure to normal or optimum levels, enhanced patient education through detailed lifestyle advice and the update of existing practice registers.**

**The slides headed 'The program guidance form' had 'Cozaar/Losartan' printed in a box beneath the heading 'Practice Policy – please complete'.**

**Another slide provided by Merck Sharp & Dohme was headed 'Implementation changes' and referred to a more focussed proforma for both programmes. This was shown on the following slide which made it clear that if the practice angiotensin antagonist of choice was not Cozaar then the practice was not suitable. If the practice had not agreed to Cozaar as the drug of choice for A in the BHS guidelines ABCD then it was not suitable. If the brick market share was not above 40% for Cozaar then the practice was not suitable. The proforma provided by the complainant was similar to that shown on the slides; it additionally included a section asking the representative for the rationale as to why it was important to nominate the surgery for the audit.**

**The medical/legal approved proformas provided by Merck Sharp & Dohme, however, were very different to those on the slides and those provided by the complainant; there were different questions to be completed and there were no criteria to be met for the practice to be deemed suitable for offering the service.**

**The HRP-GMS Protocol provided by the complainant referred to the BHS recommendations for combining blood pressure lowering medicines. It included the reference to A as 'angiotension receptor blocker or ACE inhibitor'; this matter was the subject of complaint in Case AUTH/1762/10/05 and the Panel considered that Merck Sharp & Dohme should have changed the protocol as a result of the ruling in that case.**