EMPLOYEE v SANOFI-AVENTIS and PROCTER & GAMBLE

Osteoporosis audit programmes

An anonymous complainant, writing under a pseudonym and describing himself as a current employee of Sanofi-Aventis working in the UK, alleged inappropriate service offerings by both his employer and Procter & Gamble. Procter & Gamble and Sanofi-Aventis worked together as the Alliance for Better Bone Health (ABBH) to promote Actonel (risedronate) for the treatment of osteoporosis. The services at issue had been offered by the ABBH when it consisted of Aventis, ie prior to its merger with Sanofi-Synthelabo to become Sanofi-Aventis, and Procter & Gamble.

The complainant provided a number of documents relating to the ABBH sponsored osteoporosis nurse audit programme, delivered by agency nurses, which he alleged showed that the service had been implemented in a fashion that repeatedly and unequivocally linked its provision to product usage. This was totally unacceptable and failed to adhere to both the letter and spirit of the 2003 and 2006 Codes on multiple counts. The programme ran from 2002 until 2004 involving 424 practice based audits. Seemingly, this programme was heralded as a major commercial success within the ABBH having resulted in 17,532 patients being initiated on a bisphosphonate, the vast majority on Actonel.

The complainant alleged that a substantial proportion of the nurse audit programme was concerned with steroid-induced osteoporosis. For much of the time that this programme was implemented, however, Actonel once weekly was not licensed for this indication. Accordingly, in addition to inappropriate linkage of so-called 'service to medicine' to use of the sponsor companies' product, unethical promotion of an unlicensed medicine might have been effectively conducted through this programme. If demonstrated to be true then the latter point would bring further disgrace upon the industry at best and potentially represent a threat to patient safety at worst.

The Panel considered that the complaint concerned both the nurse audit and the associated Osteoporosis Primary Care Audit Tool (TOPCAT) service.

The Panel noted that the nurse audit, which ran from 2002 until 2004, was sponsored by the ABBH which comprised Procter & Gamble and Aventis.

The Panel noted that the material for health professionals referred to the ABBH and bore a declaration of sponsorship which referred to Aventis and Procter & Gamble. Some of the documents provided by the complainant referred to the ABBH.

Case AUTH/1903/10/06 - Procter & Gamble

The Panel noted that Procter & Gamble acknowledged that as far as it was aware the Nurse Audits document supplied by the complainant had been created within Procter & Gamble in May 2004. The document clearly linked the provision of the service to the prescription of Actonel. The objectives included increasing sales by identifying new patients in Actonel friendly surgeries and increasing Actonel new patient share post audit. A section of the document was entitled 'Business Return'; the final two points made in that section were '80% of new o/p patients get Actonel – national figure 25%' and 'Increase in 35mg Actonel share from 6.6% to 26.9%'. Surgeries were nominated for the service if they were 'Actonel friendly'.

The TOPCAT Surgery Nomination Form (provided by the complainant), in a section entitled 'Checklist' also referred to Actonel - one of the checklist statements was 'Surgery preferred bisphosphonate therapy for all licensed indications is Actonel'. Completed forms were to be sent to 'your regional manger copying in ABBH colleagues'. The Panel noted Procter & Gamble's submission that the reference number on this document suggested that it had gone through the copy approval process. A flow chart for selection of TOPCAT surgeries bore an identical reference number and instructed representatives to check first of all 'Is this Surgery First Line?' The TOPCAT Briefing Document, for internal use only, (provided by the complainant) appeared to be aimed at representatives. Procter & Gamble had not commented on this document which stated that the service was for use 'where Actonel is first line'. TOPCAT was designed to complement the nurse audit programme which was described as a major strategic investment for the ABBH. It stated that based on a surgery with 5,000 patients TOPCAT would deliver an average 25 patients suitable for Actonel initiation which translated into an extra £5,200 on yearly sales per practice. It referred to the ABBH, set out a suggested sales story and stated 'representatives of Aventis (and P&G) will not …' be present or involved in certain activities.

The Panel noted Procter & Gamble's submission that it could find no evidence that the Nurse Audits document, or the TOPCAT surgery nomination form, had been supplied to the sales force. The Panel further noted Procter & Gamble's submission that it was highly likely that the Nurse Audits document was only used as a positioning document for head office staff, however the document addressed the

representatives directly, referring to 'your RBM' and summarized the representatives' role beneath the heading 'process'. The Panel queried whether such references were consistent with a head office positioning document.

The Panel noted Procter & Gamble's submission that documents used internally indicated that representatives were encouraged to identify 'Actonel first use surgeries' or 'Actonel friendly surgeries' for the nurse audit programme or TOPCAT and also that representatives should be confident that GPs would be likely to prescribe risedronate before nominating practices for inclusion in the programme. In that regard the company provided a document, Actonel GP Call Agenda and Follow Up – November 02 to January 03, which clearly showed that only when surgeries agreed to prescribe Actonel first choice or first line, were they offered the nurse audit service. A document, Programme: Update and Changes to Osteoporosis Review, was printed on Aventis and Procter & Gamble headed paper and signed by the Actonel team. It stated that assessment of the surgeries already reviewed showed there to be an increased proportion of patients already receiving bisphosphonate treatment compared to the pilot. This reduced the number of patients in each surgery that could benefit from the review. Therefore the quality of nominations needed to improve. The accompanying Sales Force Call Agenda (June 2003) again clearly linked the offer of the service to those practices which agreed to prescribe Actonel first choice.

The Panel noted that having selected practices on the basis that they prescribed Actonel first choice/first line, the documents given to customers in respect of the nurse audit programme and TOPCAT did not refer to Actonel. These documents referred to a selection of treatments; bisphosphonate, SERM and calcium and Vitamin D supplement of choice.

The Panel considered that the internal documents for the nurse audit and for TOPCAT did not meet the requirements of the 2003 Code. The documents were such that representatives would only offer the services to those surgeries that agreed to use Actonel first choice/first line. In that regard the Panel noted that Procter & Gamble had data to show that 88% of all treated patients were initiated on Actonel in the nurse audit programme between March 2003 and October 2004. In 2004 approximately 60 patients were started on Actonel as a result of TOPCAT. The Panel considered that the selection of practices for the nurse audit and TOPCAT was unacceptable; the arrangements were contrary to the requirements of the Code and a breach was ruled. This ruling was appealed.

The Panel further considered that the overall arrangements brought discredit upon the pharmaceutical industry; a breach of Clause 2 was ruled. This ruling was appealed.

The Panel decided to report Procter & Gamble to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the 2006 Constitution and Procedure.

With regard to the promotion of Actonel for corticosteroid-induced osteoporosis, the Panel noted that throughout the period of the nurse audit and of TOPCAT, Actonel 5mg was so licensed. Although Actonel 35mg was not licensed for use in corticosteroid-induced osteoporosis, there was no evidence that it had been promoted for such an indication. No breach was ruled in that regard.

Case AUTH/1902/10/06 - Sanofi-Aventis

The services in question had been run by Aventis prior to its merger with Sanofi. The Panel noted Sanofi-Aventis' submission that none of its current management team had been involved with the nurse audit; no-one from Aventis' medical or regulatory teams had transferred to the new company which had no involvement in the pre-2005 ABBH when the documents at issue were created and used. The Panel considered that Sanofi-Aventis was, nonetheless, responsible for the acts or omissions of Aventis in the past which came within the scope of the Code. Sanofi-Aventis had had to rely on incomplete records archived by Aventis to form its response. Procter & Gamble had provided Sanofi-Aventis with a copy of its response.

The Panel noted Sanofi-Aventis' comments about the logistical and other difficulties associated with the merger. Nonetheless, given Sanofi-Aventis' continuing responsibilities under the Code for acts/omissions of Aventis it was beholden upon companies wherever possible to use their best endeavours to ensure that relevant material and job bags were retained. Sanofi-Aventis should at the very least have been able to produce job bags for the relevant training material from early 2004.

The Panel noted Sanofi-Aventis' submission that it had no archived record of the documents supplied by the complainant ie the Nurse Audits document, the TOPCAT surgery nomination form and the TOPCAT briefing document. (The first document was acknowledged by Procter & Gamble, as far as it was aware, to have been drafted by it. Procter & Gamble acknowledged that the second document appeared to have gone through its certification process. In the Panel's view the TOPCAT briefing document was likely to have gone through Procter & Gamble's certification process given the similarity of its reference code to the reference code on the other two documents.) In its response Sanofi-Aventis submitted documents supplied to customers.

Nonetheless the Panel noted that the Nurse Audits document, the TOPCAT flow chart, the TOPCAT surgery nomination form and TOPCAT briefing document were originally provided by the complainant who described himself as a current employee of Sanofi-Aventis. He corresponded with the Authority under a pseudonym. The Panel was thus extremely cautious when deciding what weight to attribute to this evidence. The provision of relevant documents by a current Sanofi-Aventis

employee might be seen as inconsistent with the company's comments on the availability of documents. Nonetheless the Panel did not know how or from where the complainant had obtained the documents.

The Panel further noted Sanofi-Aventis' submission that the ABBH was a collaboration between two independent companies and that as such it was likely that the two had differing involvement and participation in particular initiatives. The Panel noted, however, that Procter & Gamble had submitted a document (Programme: Update and Changes to Osteoporosis Review) which clearly linked the two companies (it was headed with the two company logos) and which in the accompanying Sales Force Call Agenda (June 2003) clearly linked the provision of the nurse audit service to the prescription of Actonel ie call objective was to gain agreement to prescribe Actonel as first choice. The Sales Force Call Agenda referred to completing the booking form with input from 'local Alliance territory team including opposite Alliance RBM/RSM, P&G Account Executive and Aventis Hospital Rheumatology Team'. Weekly update reports would be sent to 'all Alliance RBM/RSMs including approved nominations tracker…'.

The Panel considered that the Programme: Update and Changes to Osteoporosis Review document did not meet the requirements of the Code. Sanofi-Aventis had been provided with a copy of Procter & Gamble's response by Procter and Gamble. The Authority had asked Sanofi-Aventis to comment on any differences. Sanofi-Aventis had not commented on this specific document. The document encouraged representatives to only offer the service to those surgeries which used Actonel as first choice. The Panel noted its comments above on the TOPCAT documents which referred to the ABBH and to Aventis. The Panel considered that the selection of practices for the nurse audit and TOPCAT was unacceptable; the arrangements were contrary to the requirements of the Code and a breach was ruled. This ruling was appealed.

The Panel further considered that the overall arrangements brought discredit upon the pharmaceutical industry; a breach of Clause 2 was ruled. This ruling was appealed.

The Panel decided to report Sanofi-Aventis to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the 2006 Constitution and Procedure.

With regard to the promotion of Actonel for corticosteroid-induced osteoporosis, the Panel noted that throughout the period of the nurse audit and of TOPCAT, Actonel 5mg was so licensed. Although Actonel 35mg was not licensed for use in corticosteroid-induced osteoporosis, there was no evidence that it had been promoted for such an indication. No breach was ruled in that regard.

Upon appeal in Cases AUTH/1902/10/06 and AUTH/1903/10/06, the Appeal Board noted that osteoporosis was a serious disease and that a service which would increase diagnosis and treatment would be of benefit to patients. Nonetheless any such service had to comply with the Code.

The Appeal Board was concerned about the limited documentation provided by the companies and noted their explanations in this regard. In relation to the material provided by the complainant the Appeal Board noted that whilst it was possible to contact the complainant his identity was unknown and thus it was extremely cautious when deciding what weight, if any to attach to his evidence.

The Appeal Board noted that the parties' submissions differed. Nonetheless there were some similarities between them. The complainant had provided documents which he stated were intended to be used by representatives; the companies disagreed and stated that the documents had not been used in the field. The Appeal Board ultimately concentrated on two documents regarding the nurse audit which both companies agreed had been used by sales personnel; a document headed 'Actonel GP Call Agenda and Follow Up November 02 to January 03' and the Sales Force Call Agenda (June 2003) document.

The 'Actonel GP Call Agenda and Follow Up' appeared to set out the sequence of events from a sales call to an audit call. The first instruction was 'Call objective 1: Gain agreement to Rx Actonel as 1st choice therapy for patients with low BMD [bone mineral density], [corticosteroid induced osteoporosis], patients with previous fragility fracture'. If the call objective was not achieved then representatives were given a second call objective of 'If dosing were not an issue Gain agreement to proactively Rx Actonel 1st line for [the same group of patients]'. If the answer was still no then representatives were to do the second product detail. Conversely if call objective 1 or 2 was achieved the next step was referred to as Step 1 of the Audit call which was to 'Book another appointment with the GP with a profile objective: To gain a full understanding of GP's level of interest and commitment to conducting an osteoporosis review in the practice … WITHOUT ACTUALLY OFFERING THE [nurse audit] SERVICE'. Having done that the representative then had to book an appointment with the most influential GPs in the practice to ensure that they supported an osteoporosis review. The Appeal Board considered that the document was in effect briefing material which instructed representatives how to offer the service. It appeared that representatives would not offer the service until they were sure that the doctors in the practice supported an osteoporosis review and would, as part of that review, prescribe Actonel as either first choice or first line therapy to suitable patients. The Sales Force Call Agenda (June 2003) similarly showed that a doctor's agreement to prescribe Actonel as first choice therapy was the first hurdle to being offered the service. This document also included an assessment of suitability for osteoporosis review which included a cut off of a total patient population above 3,000 for the audit service to be offered.

The Appeal Board considered that companies had to be clear and unambiguous when instructing representatives about their role in such matters. The Appeal Board considered that the link between the promotion of Actonel and the provision of the service including the selection of practices as described in the material was unacceptable. The Appeal Board did not accept the companies' submission that the two documents clearly separated the sales and non promotional call. The Appeal Board considered that neither the content or layout of either document were satisfactory in this regard. The companies' representatives acknowledged that the layout of the documents was 'unfortunate'.

As an indication as to how the service was offered in practice, the Appeal Board noted that a statement from one of Procter & Gamble's employees read 'If a particular doctor indicated that, where a bisphosphonate was indicated, he would only prescribe a product manufactured by one of our competitors (eg Fosamax) and would not consider risedronate [Actonel], then representatives would not routinely book a second appointment to discuss the Nurse Audit Programme. Nevertheless, this does not mean that practices who did not prescribe risedronate were excluded and some such practices did, in fact, participate in the Programme'.

Notwithstanding the statement that some surgeries which did not prescribe Actonel were offered the service, the Appeal Board considered that the link in the representatives' material between the promised prescription of Actonel by the doctor and the subsequent offer of the service by the representative was unacceptable. It considered that the criteria for the selection of practices and the failure to adequately separate the promotional and non promotional role of the representatives was such that the arrangements failed to comply with the Code. The Appeal Board upheld the Panel's ruling of a breach. The Appeal Board considered that the concerns about the material which gave rise to the breach were so serious that they brought discredit upon and reduced confidence in the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2.

The Appeal Board noted its comments above about the weight to be attached to the evidence. The Appeal Board considered that there was insufficient evidence to establish, on the balance of probabilities, whether the arrangements for the TOPCAT service complied with the Code. The Panel's ruling in this regard no longer stood. Accordingly, there was no breach of the Code in relation to arrangements for the TOPCAT service.

The Appeal Board noted the Panel's report in accordance with Paragraph 8.2 of the Constitution and Procedure. The Appeal Board noted its comments above and its rulings of breaches of the Code in relation to the nurse audit programme. The Appeal Board was concerned about the paucity of documentation provided by both companies. The Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require an audit of both companies' procedures in relation to the Code to include an examination of policies and procedures relating to the ABBH. On receipt of the audit reports the Appeal Board would decide if any further action was required.

Upon receipt of the audit report of Sanofi-Aventis, the Appeal Board decided that on the basis that the recommendations were implemented no further action was required.

The Appeal Board considered that the audit report of Procter & Gamble showed that there was much work still to be completed to implement the recommendations and it was concerned about the inadequacy of the certification arrangements. The Appeal Board decided that Procter & Gamble should be re-audited in January 2008.

An anonymous complainant, writing under a pseudonym and describing himself as a current employee of Sanofi-Aventis working in the UK, complained about alleged inappropriate service offerings by both his employer and Procter & Gamble Pharmaceuticals UK Limited. Procter & Gamble and Sanofi-Aventis worked together as the Alliance for Better Bone Health (ABBH) to promote Actonel (risedronate) for the treatment of osteoporosis. The complaint was taken up with both companies. The services at issue had been offered by the ABBH when it consisted of Aventis ie prior to its merger with Sanofi Synthelabo to become Sanofi-Aventis, and Procter & Gamble.

COMPLAINT

The complainant provided a number of documents relating to the ABBH sponsored osteoporosis nurse audit programme, delivered by agency nurses, which he alleged showed that the service had been implemented in a fashion that repeatedly and unequivocally linked its provision to product usage. This was totally unacceptable and failed to adhere to both the letter and spirit of the 2003 and 2006 Codes on multiple counts. The complainant deplored and was profoundly concerned to see an organisation which he had held in very high regard engaged in such unethical marketing practices on a grand scale. The programme ran from 2002 until 2004 involving 424 practice based audits. Seemingly, this programme was heralded as a major commercial success within the ABBH having resulted in 17,532 patients being initiated on a bisphosphonate, the vast majority on Actonel.

If the pharmaceutical industry was to ever enjoy the confidence of the government and the public it must strive to permanently eliminate such unethical practices. The current case involved the ABPI President's company and was therefore likely to seriously undermine confidence in the industry's ability to self-regulate. The complainant, like many colleagues in the UK pharmaceutical industry, wanted to look forward to a long and fulfilling career in the industry but he viewed recurrences of unethical practices as a major threat to that goal and would not

tolerate the malpractice of others impacting on his ability to make a living in a business to which he was completely committed. Accordingly, he requested that the Authority fast-track the current case; if necessary an emergency meeting of the ABPI Board of Management could be called within the next week. The complainant wanted to provide the industry with the opportunity to self-regulate its way out of another self-inflicted crisis. However, failure to take appropriate corrective action within four weeks of receipt of this letter ie by end-of-business on Friday, 17 November 2006, would result in alternative avenues being pursued to rectify the current ethical crisis evident across the business. The Medicines and Healthcare products Regulatory Agency (MHRA) would be the next port of call; in the unlikely event that the national regulator chose not to act rapidly on this matter then the complainant would see no alternative but to place this information in the public domain and allow the media to determine the industry's fate. The industry's reputation was clearly at its lowest ebb and so now was as good a time as any to bring the skeletons from the closet, face the music and change its ways for good.

Like many of his colleagues, the complainant felt that the UK pharmaceutical industry was sitting on a precipice in respect of its likelihood of maintaining the privilege to self-regulate its business practices. Decisive action must be taken against those who would endanger self-regulation for the consequences of the introduction of a body such as the Financial Services Authority in the industry's sphere of business would be catastrophic for its collective reputations and make day-to-day business far more cumbersome than was currently the case.

He appealed to the Authority to act decisively and fast in the matter of the ABBH osteoporosis nurse audit program.

In subsequent correspondence the complainant alleged that a substantial proportion of the nurse audit programme was concerned with steroid-induced osteoporosis. For much of the time that this programme was implemented Actonel once weekly was not licensed for this indication. Accordingly, in addition to inappropriate linkage of so-called 'service to medicine' to use of the sponsor companies' product, unethical promotion of an unlicensed medicine might have been effectively conducted through this programme. If demonstrated to be true then the latter point would bring further disgrace upon the industry at best and potentially represent a threat to patient safety at worst.

When writing to the companies, the Authority asked them to respond in relation to Clauses 2, 3.1 and 18.1 of the Code.

Case AUTH/1902/10/06 - Sanofi-Aventis

RESPONSE

Sanofi-Aventis stated that the nurse audit ran from 2002 until 2004 and was sponsored on behalf of the original ABBH members Procter & Gamble and Aventis UK. The complainant had also submitted materials which related to an associated service the osteoporosis primary care audit tool (TOPCAT).

Sanofi-Aventis was surprised at the language and content of some of these materials.

However, the programme subject to this complaint was not in existence, and had not been conducted during the tenure of the current management team of Sanofi-Aventis. The programme services were discontinued before the acquisition in December 2004 of Aventis by Sanofi.

The new Sanofi-Aventis team managed the combined operations of Sanofi and Aventis in the UK from the first quarter of 2005. Sanofi-Aventis introduced new management teams and implemented new procedures and certifying signatories.

Aventis was formed in 1999 after the merger of Rhone Poulenc Rorer and Hoechst Marion Roussel. Aventis' operational activities were based at its UK headquarters in Kent until December 2004, after which the site was closed except for IT support and postal redirection. Aventis documentation was archived without moving to the Sanofi-Aventis head-office.

The current ABBH members and their management had therefore relied on documentation archived by previous ABBH members to respond to this complaint.

Sanofi-Aventis would address key facts before responding to the allegations.

Relevant service providers

A third party nurse advisor audit support service and a third party data processing service were used.

No members of the Aventis medical or regulatory teams transferred to Sanofi's business. There was therefore virtually no transfer of know-how or of history to Sanofi. Sanofi standard operating procedures (SOPs) were implemented throughout the new operations in the first quarter of 2005.

ABBH

The ABBH was set up in 1997 in the US, and then in the UK by Procter & Gamble and Hoechst Marion Roussel, which on its merger in 1999 with Rhone Poulenc Rorer became Aventis, to share know-how and certain costs (salesforce, promotional and non-promotional services) relating to the marketing of Actonel 5mg once daily and 35mg once weekly. It was not a separate legal entity nor a co-promotion nor a joint venture. The key competitors were Fosamax once weekly, then alendronate once daily and once weekly. Evidence of the market share of osteoporosis treatments could be found in the National Institute for Health and Clinical Excellence (NICE) Technology Appraisal No 87.

Overview of documents and services

Sanofi-Aventis had found documents pertaining to an ABBH nurse audit programme and the TOPCAT service. These were certified by the signatories of the historical ABBH members, Aventis and Procter & Gamble and a copy was provided.

Sanofi-Aventis had no archived record of the documents submitted by the complainant and in particular the Nurse Audits document (ref CP&S UK MDO), the TOPCAT Surgery Nomination Form (ref ACT 7330504) and the TOPCAT Briefing Document (ref ACT 8070904). Sanofi-Aventis had been unable to ascertain the origin or creator of these documents for the reasons explained above.

Nurse Audit Programme

Sanofi-Aventis provided copies of the 2002 versions of the Osteoporosis Review Document and the Osteoporosis Review Consent Documentation in order to demonstrate the context of implementation of the services. The company submitted that the audit programme followed a detailed protocol which incorporated best practice guidelines by two different case selection methods. The first identified patients with osteoporosis and/or with a high risk of fracture or further fracture who qualified for immediate treatment. The second included patients with osteoporosis risk factors, but with an unconfirmed diagnosis, warranting a scan to establish appropriate management. The criteria for patient identification were based on the Royal College of Physicians (RCP) guidelines and agreed with the practice.

Informed consent was obtained from the patients. Identified patients had the necessary information relevant for the management of osteoporosis captured and, on completion, these data were presented to the practice. The GP then invited appropriate patients for consultation at the practice using the services of the nurse team. A scan (provided as part of the service) was offered to confirm the diagnosis of osteoporosis in those patients where the information from the scan would alter management or be clinically indicated.

All management or treatment decisions were based on protocols following best practice and approved by the patient's doctor. Given the menu of treatment options, the decision analysis as to the appropriate treatment or management lay with the patient's doctor.

It appeared that representatives could discuss the service in a non-promotional call with practices which would then be prepared to be nominated practices; however, GPs interested in the audit service could also approach the nurses independently. The service was therefore provided primarily to practices which were existing prescribers of Actonel, or to new prescribers of Actonel only in compliance with RCP guidelines and later NICE guidelines, but also to prescribers of other treatments including calcium who requested the services.

The nurse audit appeared to have commenced as a pilot service in late 2001 and was discontinued effective 31 October 2004.

TOPCAT

Sanofi-Aventis provided a 2004 copy of TOPCAT, a patient care tool to help a practice identify patients by using software which screened Read and Drug Codes. Those patients' identified management was reviewed and amended according to the GP's wishes and based on best practice and NICE guidelines. Sanofi-Aventis did not know when the TOPCAT service was discontinued.

Briefing materials to representatives and to the nurse advisor audit service

Aventis representatives were trained on line. For example, Sanofi-Aventis had found 2004 records which demonstrated how Aventis provided training and briefing. It appeared Procter & Gamble briefed the nurse advisor service.

The provision and offer of both the audit service and TOPCAT service would have been subject to the requirements of Clause 18.1 'Provision of Medical and Educational Goods and Services' of the 2001 and 2003 Codes.

Clause 18.1

The nurse advisor audit and TOPCAT services were designed to enhance patient care or benefit the NHS as outlined in the programme overviews. From archived documents Sanofi-Aventis had found no evidence that the services were directly linked to product usage. In verifying the complainant's allegations, Sanofi-Aventis contacted prescribers for their views and one opinion was provided.

In 'Our Healthier Nation', the Secretary of State for Health highlighted the role of osteoporosis in causing fractures in older people noting that, as a result of this disease, falls were a major cause of death and disability. Osteoporosis prevention was therefore included as one the measures recommended to help achieve a 20% reduction in fractures by 2010.

The osteoporosis review incorporated guidance from various osteoporosis guidelines (best practice). In addition the material recognised that each individual practice or local health authority might already have its own policies in place. In summary these audits appeared to have been appropriate services based on sound rationale, designed for the benefit of patients under the full control and discretion of prescribers.

With regard to the supplementary information to Clause 18.1, Sanofi-Aventis noted the following: The services provided to GP practices (review of records to identify patients at risk of osteoporosis without disclosure of confidential information and in accordance with GP's instructions) were performed by teams of qualified nurses, who held full Nursing and Midwifery Council (NMC) accreditation and who had received specialist training in clinical audit and the

needs of osteoporotic patients. These nurses were employed by a third party, not by Procter & Gamble or Aventis (paragraph 1 (i-iv)).

Furthermore it appeared patient safety was not compromised: NICE guidelines which recommended alendronate, etidronate and risedronate as first line treatment options were followed; clear protocols were drawn up which gave prescribers unrestricted treatment options. It appeared that representatives provided information about the service in non-promotional calls and forwarded the names of interested practices to the independent service providers.

The audit programme conformed to the requirements of the General Medical Council (GMC) Guidelines, Data Protection Act 1998 and the Caldicott Principles to ensure patient confidentiality (paragraph 1 (v)).

The independent nurses were registered and their role complied with the NMC Code of Professional Conduct (paragraph 1 (vi)).

It appeared that the remuneration of the independent nurses was not linked to sales (paragraph 2).

The services conformed to the Data Protection Act 1998. Any clinical data, which might have been collected for research purposes, were anonymised. It appeared the programme sponsors received monthly reports of data, anonymised so that individual patients could not be identified. The written consent of the patient's doctor for the provision of the service in accordance with doctor's instructions was always obtained prior to commencement of the service (paragraph 3).

The audit complied with the terms of an approved protocol, protocol documents and consent forms (paragraph 4).

The independent nurses followed a protocol when introducing themselves to the interested practice, which included transparency regarding the identity of the sponsors (paragraph 5).

The protocol documents clearly outlined the service in detail and were explicit about the sponsors' identity. Data collection and analysis followed a strict protocol. Data were collected using the practice computer and patients' notes. The information was recorded in a register which was left with the practice at the end of the review. The report included all the data and information collated from the patient register and clinical reviews conducted by the independent nurse advisor. In addition, general observations along with any specific practice recommendations in line with existing guidelines for the management of osteoporosis were compiled (paragraph 6).

All the materials were disease orientated and hence consistent with the principles of audit as service to medicine. They were non-promotional, aligned to the current treatment guidelines and did not mention any specific products. The identity of the sponsors was clear in all aspects of the programme (paragraph 7).

Materials relating to the service were examined by the then certifying signatories of the historical ABBH (paragraph 8).

The audit service was a net contributor to the budget of a primary care trust (PCT). This was achieved indirectly through cost savings on fracture related treatment and screening. The biggest bottle-neck to diagnosis and treatment was scanning which was also costly. As part of the audit service a mobile scanning service was made available (paragraph 9).

In its guidance, the GMC advised doctors that 'you must act in your patients' best interests when making referrals and providing or arranging treatment or care'. The audit service, in its design and conduct, increased a clinician's capacity to manage osteoporosis and enhanced patient care and improved quality of life.

Clause 3.1

The protocol followed best practice guidelines and left all treatment and management decisions to prescribing doctors. Sanofi-Aventis had no evidence that the service promoted any of the medicines used for the management of osteoporosis outside their licensed indications.

As regards the allegation that Actonel 35mg was promoted outside of its licensed indications between 2002 and 2004 it was clear that Actonel 5mg od was licensed throughout this time for corticosteroid-induced osteoporosis and that Actonel 35mg once a week was approved in January 2003 for postmenopausal osteoporosis (PMO).

The decision to prescribe any medication, whether Actonel or any other treatment, was entirely that of the GP who approved use of the services.

Clause 2

From documents available to Sanofi-Aventis, it appeared that the services were provided as a service to medicine, designed and implemented to address an important need of practices, for the benefit of patients. It appeared that certified documents demonstrated how under the 2001 and 2003 Codes the services had not brought discredit to the industry and appeared to have generated positive feedback from GPs.

The services were moreover provided by the historical ABBH members which had different management and processes.

Conclusion

Applying the requirement of the 2001 and 2003 Codes, the documents available to Sanofi-Aventis showed that service provision was not directly linked to product usage and complied with applicable guidelines and best practice.

The services were sponsored by the historical ABBH

members between 2002 and 2004. The management and signatories of Sanofi-Aventis had no involvement, influence or other participation in those activities, and had no control over the conduct of the activities or of the archiving of materials or records.

In response to a request for further information Sanofi-Aventis explained that it had reviewed any paper and electronic records it could find and asked Procter & Gamble to search its own records. The logistical difficulties facing the newly merged company were that paper records located at the Aventis headquarters in Kent, if they were retained, were significantly incomplete and archiving records were also incomplete.

It was up to each former Aventis business unit director as to whether electronic records were saved. As none of the former Aventis medical, regulatory, legal or quality control employees who worked on Actonel in 2004 transferred to Sanofi-Aventis in Guildford, there was no formal transfer of electronic records.

As Sanofi-Aventis did not know which records existed before the integration, it could not ascertain whether records had been transferred, archived or destroyed. Furthermore, changes to e-mail and representative's software caused laptop drives to be cleared and replaced with new software in the first quarter of 2005. Sanofi-Aventis was thus entirely reliant on paper or electronic records which might have been informally provided to individual staff of Sanofi during the transition to Guildford, and on documents which appeared, on an inconsistent basis, to have been retained (for example in legal records). Unsurprisingly, most such documents transferred to Guildford appeared to have been created in 2004.

Sanofi-Aventis was thus required to try to understand from those few documents available to it and Procter & Gamble, often out of context, the facts as well as the background to the documents themselves. However, it was clear that Sanofi-Aventis, formed in 2005, would have had no control over the creation, the use or the archiving of documents created and used before that time, and had no involvement in the pre-2005 ABBH when these documents were created or used.

In response to a request for comments on the fact that Procter & Gamble's response was different to that of Sanofi-Aventis, Sanofi-Aventis explained that the ABBH was and continued to be a collaboration between two independent companies. It was therefore likely that the two companies had differing involvement and participation in particular initiatives relating to Actonel.

The ABBH was first constituted in 1997 as an agreement between Hoechst Marion Roussel and Procter & Gamble in the US. After the merger of Hoechst Marion Roussel and Rhone Poulenc Rorer in 1997, to form Aventis, the alliance was extended to other countries. Procter & Gamble had developed Actonel and launched it in the UK in May 2000. Other than the worldwide 1997 agreement, there was no detailed agreement between Aventis and Procter & Gamble relating to the UK ABBH. From anecdotal evidence Sanofi-Aventis understood that Procter & Gamble and Hoechst Marion Roussel, which became Aventis, shared certain marketing costs, and met on a monthly basis to discuss marketing initiatives and review Actonel sales. There were however no common resources (for example salesforce representatives), offices or computer networks. Each company had its own SOPs regarding certification and sign-off of materials.

Sanofi-Aventis could not comment upon the actions of Procter & Gamble relating to Actonel and the programme, its documents or internal procedures. Procter & Gamble had confirmed that it accepted only a breach of Clause 14.1 of the 2003 Code, having regard to the inconsistency of certification of internal briefing materials intended for use with its own representatives (not with Aventis representatives) in the course of offering the programme.

Sanofi-Aventis stated that after an extensive investigation of documents which had become available to it and Procter & Gamble, it had no evidence to indicate that Aventis' involvement in the programme was in breach of the Code.

Sanofi-Aventis noted that the complaint related to events which had occurred between 2002 and 2004, prior to the acquisition of Aventis by Sanofi, which was concluded in December 2004. At these material times, the current activities and management of Sanofi-Aventis did not exist and could therefore have had no knowledge of, or control or involvement in pre-2005 matters. Moreover, Sanofi's and Aventis' pre- and post-2005 operations were conducted using separate legal entities: Sanofi from Sanofi-Synthelabo Limited, whereas Aventis traded out of various companies including Fisons Limited, May & Baker Limited and Aventis Pharma Limited.

Although Sanofi-Aventis had no evidence to suggest any breach of the Code by Aventis it also did not believe that it would be appropriate for any other company to be asked to accept responsibility for activities undertaken historically by Aventis.

Sanofi-Aventis reiterated that Aventis and Procter & Gamble appeared to have each retained and used their own SOPs.

The relevant Aventis SOP, 'Communication Material Approval', was effective from November 2003, and reviewed in November 2004. Although it referred to a Communication Material Central Database, no such database had been mentioned by any former Aventis director and none had been found or transferred to Sanofi-Aventis.

Procter & Gamble and Sanofi-Aventis had also found a pro-forma Actonel Alliance Copy Approval Form dating about 2003. There was no detailed ABBH SOP associated with the use of the forms. It therefore appeared from the form headings that the pre-2005 ABBH members jointly reviewed promotional and non-promotional materials intended for use with third

parties. Sanofi-Aventis did not know if there was any joint review of internal training or briefing materials – anecdotal evidence suggested that the two companies reviewed their own internal communications.

Sanofi-Aventis explained that, as with any corporate reorganisation, the acquisition of Aventis by Sanofi was associated with substantial upheaval and the possibility that relevant Aventis documents were misplaced during that time. Sanofi-Aventis could thus not comment on the potential involvement of Aventis in relation to hypothetical material, which Sanofi-Aventis had not seen.

Sanofi-Aventis also did not believe it would be appropriate for another company to be asked to accept responsibility for such documents when it had no control, involvement or knowledge of them. No manager or signatory of Sanofi-Aventis had been able to review such documents before their use.

Sanofi-Aventis submitted that none of the documents currently available to Sanofi-Aventis supported the complainant's allegations or indicated any breach of the Code on the part of Aventis.

Case AUTH/1903/10/06 - Procter & Gamble

RESPONSE

Procter & Gamble stated that it and Sanofi-Aventis currently collaborated in the marketing of Actonel as the ABBH. The ABBH was formed in 1997; during the life of the Alliance Procter & Gamble's partners had changed in accordance with the company history of Sanofi-Aventis. Procter & Gamble management and other personnel had changed during this period. At the time of the nurse audit programme, Procter & Gamble's partner was Aventis. The ABBH sponsored the osteoporosis nurse audit programme between 2002 and 2004. At the same time the ABBH also sponsored a pilot form of an associated audit tool, TOPCAT.

In 'Our Healthier Nation', the Secretary of State for Health highlighted the role of osteoporosis in causing fractures in older people noting that, as a result of this disease, falls were a major cause of death and disability. Osteoporosis prevention was therefore included as one of the measures recommended to help achieve a 20% reduction in fractures by 2010. The services were thus designed to enhance patient care or benefit the NHS.

After a thorough review of materials, Procter & Gamble appreciated that some of its actions infringed the 2001 and 2003 Codes. It apologised for these past actions, and had taken the appropriate steps to ensure they did not occur again. New policies and procedures had been put in place since these programmes were initiated so as to prevent these types of errors in the future.

Description of audit programmes

Nurse Audit Programme

Procter & Gamble explained that this audit programme ran from July 2002 to November 2004 and followed a detailed protocol which incorporated best practice guidelines, adapted to the needs of individual GP practices. Patients at risk of osteoporosis were identified in surgeries by trained nurses using two different case selection methods. The first identified patients with osteoporosis and/or with a high risk of fracture or further fracture who qualified for immediate treatment. The second included patients with osteoporosis risk factors, but with an unconfirmed diagnosis, warranting scanning to establish appropriate management. The criteria for patient identification were based on the RCP guidelines, and agreed with the practice.

Informed consent was obtained from all patients. Patient information relevant for the management of osteoporosis was captured and these data were presented to the practice. The GP then invited appropriate patients for consultation at the practice using the services of the nurse team. A scan (provided as part of service) was offered to confirm the diagnosis of osteoporosis in those patients where the information from the scan would alter management or be clinically indicated. All management or treatment decisions were based on protocols following best practice and approved by the patient's doctor. The decision on the appropriate treatment or management lay with the patient's doctor.

ABBH representatives promoting Actonel could nominate practices for involvement in the audit programme via a non selling call.

TOPCAT

TOPCAT was initiated as a pilot programme in May 2004. This was a comprehensive electronic audit patient care tool, designed to help a practice identify patients by using software which screened Read and Drug Codes.

The software was mailed to the surgeries, which ran the software through their patient records to identify patients who might benefit from osteoporosis therapy. The clinical management of identified patients was reviewed and amended if appropriate according to the wishes of the GP and based on best practice. Additional features of the programme included guidance on how practices could improve their performance consistent with specific indicators included in the new General Medical Services (GMS) contract and Quality and Outcomes Framework. The service also included disease information for patients.

ABBH representatives promoting Actonel could nominate practices for use of the TOPCAT audit tool via a non selling call.

Roles of each party

The ABBH developed the materials for the programmes and paid for the nurses. Materials used externally were prepared and approved for use by both companies. Representatives from the two companies identified surgeries for inclusion in the programmes.

The two members of the ABBH jointly agreed the programmes and assigned leadership across the ABBH for different aspects of the work.

In the case of TOPCAT, the programme was agreed by both companies, and executed by Procter & Gamble. A CD-ROM was distributed by a third-party supplier to GP practices for use in practice computer systems to identify potential osteoporotic patients. Data from the programme was analysed by the third party.

Process by which surgeries were selected

Representatives nominated surgeries for inclusion in the audit programme if: there was more than one GP in the practice; the practice had a patient population above 3000; no osteoporosis related review had been conducted in the last 2 years; more than 20% of the patients in the surgery were >60 years of age; all practice partners agreed to having practice records searched by the nurse and GPs in the practice were known to prescribe Actonel for use in osteoporosis.

In the case of TOPCAT, surgeries were nominated to receive access to the audit tool if: they were not suitable for the nurse audit programme nomination (too few patients); no osteoporosis audit had been conducted within last 3 years; the practice agreed to initiate treatment once patient records were audited; the service was compatible with surgery records management systems and GPs in the practice were known to prescribe Actonel for use in osteoporosis.

Process by which treatment was initiated

The nurse identified patients who might benefit from therapy for osteoporosis. The physician then determined the best treatment for the patient.

In the case of TOPCAT, the programme allowed a particular surgery to manage patients in a variety of ways. One option was for the system to generate a letter which invited the patient into the surgery for a consultation, at which time the doctor would decide the most appropriate treatment. An alternative was for the system to generate a letter to which the doctor could attach a prescription to send to the patient. The option to be followed was determined by the individual doctor.

Percentage of patients initiated on Actonel

From data provided from the nurse audit programme, from March 2003 to October 2004, 351 practices were audited, involving 2,203,612 patients. 28,280 patients were invited for screening by their GPs, of which 16,759 were treated with any therapy. 15,046 (53%) of screened patients were treated with Actonel (88% of all treated patients).

From the TOPCAT programme, 72 practices were nominated for use of this audit tool in 2004, involving 272,322 patients. 2,956 patients were identified as being at risk of osteoporosis. Approximately 60 patients were initiated on Actonel therapy in this timeframe.

For perspective, approximately 163,000 patients were treated with Actonel from March 2003 to October 2004. The NICE Guidelines 2005 stated that in 2003/4, the market share for Actonel was 16% of bisphosphonate prescriptions in England. Alendronate market share was 61%, and etidronate market share was 23%.

Documents relating to the programmes

Procter & Gamble had searched its records for the two documents provided by the complainant. Procter & Gamble did not systematically archive electronic messages, however, the Nurse Audits document (ref CP&S UK MDO), had been found in an electronic archive saved as 'details of nurse programme', and dated from 7 May 2004. As far as Procter & Gamble could establish, this document was drafted within Procter & Gamble for internal head office use, and was not circulated to any sales representatives.

The reference number of the TOPCAT Surgery Nomination Form (ACT 7330504) suggested it went through the official Procter & Gamble copy approval process. This had been discovered as an electronic file, however, this had not been found in Procter & Gamble's archives of certified materials. It was possible that this was destroyed in a fire at the Procter & Gamble off-site storage facility in July 2006. Neither Procter & Gamble nor Sanofi-Aventis could find anything to indicate that this specific version of the document was deployed to the sales force in either company.

Clause 18.1

The nurse audit and TOPCAT services were designed to enhance patient care or benefit the NHS as outlined in the programme overviews. The programme incorporated guidance from various osteoporosis best practice guidelines. In addition the programme materials recognised that each individual practice or health authority might already have its own policies. In summary, the ABBH believed these audits were appropriate services based on sound rationale designed for the benefit of patients under the full control and discretion of prescribers.

With regard to the supplementary information to Clause 18.1, Procter & Gamble noted the following: the services provided to GP practices (review of records to identify patients at risk of osteoporosis without disclosure of confidential information and in accordance with GP's instructions) were performed by teams of qualified nurses, who held full NMC accreditation and who had received specialist training in clinical audit and the needs of osteoporotic patients. These nurses were employed by a third party, not by Procter & Gamble or Aventis. No product name appeared on external materials used in the programme, and materials were clearly marked as being sponsored by the ABBH. The sales representatives involved in recruiting practices into the programme carried out two separate calls. One was an Actonel sales call and the second an 'Osteoporosis Review Call'. The second call was devoted to determining if GPs would be interested in becoming involved in the programme and did not involve any promotion (paragraph 1 (i-iv)).

The audit programmes conformed to the requirements of the GMC Guidelines, Data Protection Act 1998 and The Caldicott Principles to ensure patient confidentiality. Neither the ABBH nor its representatives had access to any information that could be linked to particular patients (paragraph 1 (v)).

The independent nurses were registered and their role complied with the NMC Code of Professional Conduct (paragraph 1 (vi)).

The remuneration of the independent nurses was not linked to sales (paragraph 2).

The services conformed to the Data Protection Act 1998. Any clinical data, which might have been collected for research purposes, were anonymised. The programme sponsors received anonymised monthly reports of data, such that neither individual patients nor GPs could be identified. The written consent of the patient's doctor for the provision of the service in accordance with doctor's instructions was always obtained prior to commencement of the service (paragraph 3).

The audit complied with the terms of an approved protocol, protocol documents and consent forms (paragraph 4).

The independent nurses followed a protocol when introducing themselves to the interested practice, which included transparency regarding the identity of the sponsors (paragraph 5).

The protocol documents clearly outlined the service in detail and were explicit about the sponsors' identity. Data collection and analysis followed a strict protocol. Data were collected using the practice computer and patients' notes. The information was recorded in a register which was left with the practice at the end of the review. The report included all the data and information collated from the patient register and clinical reviews conducted by the independent nurse advisor. In addition, general observations along with any specific practice recommendations in line with existing guidelines for the management of osteoporosis were compiled. If the practice requested, a presentation of the findings was made (paragraph 6).

All the materials provided to the nurses and GPs were disease orientated and hence consistent with the principles of audit as a service to medicine. They were non-promotional, aligned to the current treatment guidelines and did not mention any specific products. The identity of the sponsors was clear in all aspects of the programme (paragraph 7).

Materials relating to the service provided to the GPs were examined by the certifying signatories of the ABBH (paragraph 8).

The audit service was a net contributor to the budget of a PCT. This was achieved indirectly, through cost savings on fracture related treatment and screening. The biggest bottle-neck to diagnosis and treatment was scanning which was also costly. As part of the audit service a mobile scanning service was made available. In its guidance, the GMC advised doctors that 'you must act in your patients' best interests when making referrals and providing or arranging treatment or care' (paragraph 9).

The services were not designed by the ABBH as an inducement to prescribe Actonel. Company personnel involvement extended to nominating practices for the service. All documents provided to GPs were reviewed and approved via the ABBH-agreed copy approval system and complied fully with the 2001 and 2003 Codes. These documents did not suggest that the services might not be offered to practices unless Actonel prescribing would result and hence the GP was not led to believe that he could not participate in the programme unless he prescribed Actonel. This supported the ABBH position that the provision of the service to individual GPs was not an inducement to the doctor to prescribe Actonel.

There was no evidence that practices who wanted to participate in the programme were excluded from this audit service because of a requirement relating to their prescription intent. Furthermore, given the NICE guidance which recommended alendronate, etidronate and Actonel as first line treatment options it was inconceivable that the nomination of 'Actonel friendly' practices would compromise choice given the well established treatment guidelines, the clear protocols as part of the audit service and the market leadership of alendronate.

Although none of the information provided to the GPs could be considered to represent an inducement to prescribe, it was recognised that internal documents encouraged representatives to identify 'Actonel first line surgeries' or 'Actonel friendly surgeries' for inclusion in the audit programmes. The documents also indicated that representatives should be confident that GPs would likely prescribe Actonel before nominating practices for inclusion in the programme.

Procter & Gamble acknowledged that the use of some of the internal documents associated with the programme could be considered to have been inappropriate, and thus render the audit programmes in breach of Clause 18.1 of the 2003 Code. In addition, its investigations had indicated that at that time the internal instructions to the sales force did not undergo the appropriate certification process required by the Code (supplementary information, section 18.1.8). Procter & Gamble took this matter very seriously and regretted that such infringements had occurred. The necessary steps to remedy these failings were already in hand.

Recognising the need to improve the rigour of its approval process for non-standard promotional materials, the ABBH introduced a new electronic system for the approval of promotional materials in October 2005. Procter & Gamble internal sales direction communications were now included in the system and all materials used in the most recent programmes had been approved.

Clause 3.1

The complainant alleged a breach of Clause 3.1, since 'a substantial portion of the ABBH nurse programme was concerned with steroid-induced osteoporosis'. Procter & Gamble noted that Actonel was available as 5mg, 30mg, and 35mg tablets. The 5mg tablets were indicated for corticosteroid-induced osteoporosis as well as PMO. The 35mg tablet was approved in January 2003 and was indicated for PMO. The 30mg tablet was indicated for treatment of Paget's disease of bone.

There was no suggestion or evidence that the audit programmes were used to promote the use of Actonel or any other therapy as part of the programme. It was true that one of the criteria used to identify osteoporotic patients was the use of corticosteroids, in line with the RCP guidelines. However, the representative played no part in the identification of patients, or decisions on their treatment, and the audit programmes were never used to promote the use of any specific medicine. On identification by the nurse of a patient with corticosteroid-induced osteoporosis, the treatment options for that patient were determined by her GP. This might have been Actonel 5mg tablets, in accordance with the licensed indications.

Clause 2

These respectable support programmes, provided as a service to medicine, were designed and implemented to address an NHS need for the benefit of patients. It appeared, from the certified documents, that under the 2001 and 2003 Codes the services had not brought discredit upon the industry.

Summary

In conclusion, this valuable service to medicine did not directly link service provision to product usage. The service was implemented by independently trained and appropriately qualified nurses. The osteoporosis review did not compromise clinician choice or patient safety, as all clinical management decisions were left to the doctor and patient. As a disease management audit, all treatment options were available to the doctor.

Applying the requirements of the 2001 and 2003 Codes, it appeared from the documents available that the services did not act as an inducement for the doctor to prescribe Actonel since neither the materials provided to surgeries nor the discussions held with the GPs linked the promotion of Actonel or the doctor's prescribing habits with the service provision.

It was acknowledged that some of the historical internal materials might not have complied with the Code. Also the review and certification of internal documents was incomplete. In view of this, Procter & Gamble's internal procedures were undergoing comprehensive review, and new training would be provided to ensure that such situations could not arise in the future.

In response to a request for further information with regard to the Nurse Audits document supplied by the complainant (ref CP&S UK MDO), Procter & Gamble submitted it was created within the company on 7 May 2004. The reference code strongly suggested that this was a Procter & Gamble document, as this was clearly company terminology describing the UK head office based commercial team - Customer Planning and Strategy.

The document was stored in an archive of draft and final documents used at 2004 sales conferences. The archived documents relevant to the nurse audit programme included a presentation by the project leader, draft and final documents for the March 2004 sales conference and a proposed agenda for the May 2004 sales conference including details of a portion of the meeting to be led by the Procter & Gamble and Aventis commercial managers responsible for the nurse audit programmes.

Procter & Gamble did not believe that the document provided by the complainant was shared with representatives, since it was created in May 2004 and was not mentioned in the agenda for the May meeting. It was highly likely that it was only used as a positioning document for the head office team.

With regard to the certification arrangements for materials used externally in the audit programmes, the agreed, appropriate procedure was that Aventis and Procter & Gamble certified such materials. A template signatory sheet which was used in 2004 was provided. The originator company (ie Procter & Gamble or Aventis) filed the original document and a copy was sent to the partner for duplicate filing.

Core product training manuals were approved using standard copy approval procedures and final certification (by both ABBH partners) prior to dissemination. However, sales direction regarding programmes such as the nurse audit, were not consistently reviewed and/or certified at that time. This oversight had since been rectified. Due to the time elapsed, and changes in company personnel, it was not possible to declare that all sales directions and related materials issued by either company were known to the other party.

Procter & Gamble acknowledged that not all internal briefing materials were certified appropriately. Specifically, this admission applied to Clause 14.1, as referenced in point 8 of the supplementary information to Clause 18.1. The company did not admit to a breach of Clause 18.1. In addition, as previously stated, all materials provided to the medical community complied with the Code. For this reason, Procter & Gamble did not believe that the programme brought discredit upon, or reduced confidence in the pharmaceutical industry and hence did not in its view represent a breach of Clause 2.

PANEL RULING

The Panel considered that the complaint concerned both the nurse audit and the associated TOPCAT service.

The Panel noted that the nurse audit, which ran from 2002 until 2004, was sponsored by the ABBH which comprised Procter & Gamble and Aventis. Aventis had since merged with Sanofi to become Sanofi-Aventis.

The Panel noted that the material for health professionals referred to the ABBH and bore a declaration of sponsorship which referred to Aventis and Procter & Gamble. Some of the documents provided by the complainant referred to the ABBH.

The Panel noted that the nurse audit ran from 2002 until 2004. Clauses 2, 3.1 and 18.1 of the 2003 Code were the same as Clauses 2, 3.1 and 18.1 of the 2001 Code. Thus the Panel considered the matter under the 2003 Code. The supplementary information to Clause 18.1 of the 2001 Code was the same as the supplementary information to Clause 18.1 of the 2003 Code ie that medical and educational goods and services which enhanced patient care or benefited the NHS could be provided within certain conditions. The 2006 Code was changed to make it clear that medical and educational goods and services which benefited the NHS had, at the same time, to 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 Panel noted that the cases now before it were being considered under the 2003 Code using the 2006 Constitution and Procedure.

Case AUTH/1903/10/06 - Procter & Gamble

The Panel noted Procter & Gamble's submission regarding the roles of each party ie the ABBH developed the materials for the programmes and paid for the nurses. Materials used externally were copy approved by the ABBH. Procter & Gamble also stated that sales representatives from the two companies identified surgeries for inclusion in the programmes. In this regard Procter & Gamble referred to the Actonel GP Call Agenda and Follow Up document and the Programme: Update and Changes to Osteoporosis Review document. TOPCAT was agreed and sponsored by the ABBH. The ABBH representatives could nominate practices for TOPCAT which was executed by Procter & Gamble.

The Panel noted that Procter & Gamble acknowledged that as far as it was aware the Nurse Audits document (ref CP&S UK MDO) supplied by the complainant had been created within Procter & Gamble on 7 May 2004. The document clearly linked the provision of the service to the prescription of Actonel. The objectives included increasing sales by identifying new patients in Actonel friendly surgeries and to increase Actonel new patient share post audit. A section of the document was entitled 'Business Return'; the final two points made in that section were '80% of new o/p patients get Actonel – national figure 25%' and 'Increase in 35mg Actonel share from 6.6% to 26.9%'. Surgeries were nominated for the service if they were 'Actonel friendly'.

The TOPCAT Surgery Nomination Form (provided by the complainant), in a section entitled 'Checklist' also referred to Actonel - one of the checklist statements was 'Surgery preferred bisphosphonate therapy for all licensed indications is Actonel'. Completed forms were to be sent to 'your regional manger copying in ABBH colleagues'. The Panel noted Procter & Gamble's submission that the reference number on this document (ACT 7330504) suggested that it had gone through the copy approval process. A flow chart for selection of TOPCAT surgeries bore an identical reference number (ACT7330504) and instructed representatives to check first of all 'Is this Surgery First Line?' The TOPCAT Briefing Document, for internal use only, (provided by the complainant) had a reference number (ACT 8070904) and appeared to be aimed at representatives. Procter & Gamble had not commented on this document which stated that the service was for use 'where Actonel is first line'. TOPCAT was designed to complement the nurse audit programme which was described as a major strategic investment for the ABBH. It stated that based on a surgery with 5,000 patients TOPCAT would deliver an average 25 patients suitable for Actonel initiation which translated into an extra £5,200 on yearly sales per practice. It referred to the ABBH, set out a suggested sales story and stated 'representatives of Aventis (and P&G) will not …' be present or involved in certain activities.

The Panel noted Procter & Gamble's submission that it could find no evidence that the Nurse Audits document, nor the TOPCAT Surgery Nomination Form, had been supplied to the sales force'. The Panel further noted Procter & Gamble's submission that it was highly likely that the Nurse Audits document was only used as a positioning document for head office staff, however the document addressed the representatives directly, referring to 'your RBM' and summarized the representatives' role beneath the heading 'process'. The Panel queried whether such references were consistent with a head office positioning document.

The company had not commented on the TOPCAT Briefing Document. The Panel noted Procter &

Gamble's submission that internal documents encouraged representatives to identify 'Actonel first use surgeries' or 'Actonel friendly surgeries' for the nurse audit programme or TOPCAT and also that representatives should be confident that GPs would be likely to prescribe risedronate before nominating practices for inclusion in the programme. In that regard the company provided a document, Actonel GP Call Agenda and Follow Up – November 02 to January 03, which clearly showed that only when surgeries agreed to prescribe Actonel first choice or first line, were they offered the nurse audit service. The Programme: Update and Changes to Osteoporosis Review (ref A2121), was printed on Aventis and Procter & Gamble headed paper and signed by the Actonel team. It stated that assessment of the surgeries already reviewed showed there to be an increased proportion of patients already receiving bisphosphonate treatment compared to the pilot. This reduced the number of patients in each surgery that could benefit from the review. Therefore the quality of nominations needed to improve. The accompanying Sales Force Call Agenda (June 2003) (also with the reference code A2121) again clearly linked the offer of the service to those practices which agreed to prescribe Actonel first choice.

The Panel noted that having selected practices on the basis that they prescribed Actonel first choice/first line, the documents given to customers in respect of the nurse audit programme and TOPCAT did not refer to Actonel. These documents referred to a selection of treatments; bisphosphonate, selective oestrogen-receptor modulator (SERM) and calcium and Vitamin D supplement of choice.

The Panel considered that the internal documents for the nurse audit and for TOPCAT did not meet the requirements of Clause 18.1 of the 2003 Code. The documents were such that representatives would only offer the services to those surgeries that agreed to use Actonel first choice/first line. In that regard the Panel noted that Procter & Gamble had data to show that 88% of all treated patients were initiated on Actonel in the nurse audit programme between March 2003 and October 2004. In 2004 approximately 60 patients were started on Actonel as a result of TOPCAT. The Panel considered that the selection of practices for the nurse audit and TOPCAT was unacceptable and this meant that the arrangements were contrary to the requirements of Clause 18.1 and ruled accordingly. This ruling was appealed.

The Panel further considered that the overall arrangements brought discredit upon the pharmaceutical industry; a breach of Clause 2 was ruled. This ruling was appealed.

The Panel decided to report Procter & Gamble to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the 2006 Constitution and Procedure. With regard to the promotion of Actonel for corticosteroid-induced osteoporosis, the Panel noted that throughout the period of the nurse audit and of TOPCAT, Actonel 5mg was so licensed. Although Actonel 35mg was not licensed for use in corticosteroid-induced osteoporosis, there was no evidence that it had been promoted for such an indication. No breach of Clause 3.1 was ruled.

Case AUTH/1902/10/06 - Sanofi-Aventis

The service offerings in question had been run by Aventis prior to its merger with Sanofi. The Panel noted Sanofi-Aventis' submission that none of its current management team had been involved with the nurse audit; no-one from Aventis' medical or regulatory teams had transferred to the new company which had no involvement in the pre-2005 ABBH when the documents at issue were created and used. The Panel considered that Sanofi-Aventis was, nonetheless, responsible for the acts or omissions of Aventis in the past which came within the scope of the Code. Sanofi-Aventis had had to rely on incomplete records archived by Aventis to form its response. Procter & Gamble had provided Sanofi-Aventis with a copy of its response.

The Panel noted Sanofi-Aventis' comments about the logistical and other difficulties associated with the merger. Nonetheless, given Sanofi-Aventis' continuing responsibilities under the Code for acts/omissions of Aventis it was beholden upon companies wherever possible to use their best endeavours to ensure that relevant material and job bags were retained. Sanofi-Aventis should at the very least have been able to produce job bags for the relevant training material from early 2004.

The Panel noted Sanofi-Aventis' submission that it had no archived record of the documents supplied by the complainant ie the Nurse Audits document, the TOPCAT Surgery Nomination Form and the TOPCAT Briefing Document. (The first document was acknowledged by Procter & Gamble, as far as it was aware, to have been drafted by it. Procter & Gamble acknowledged that the second document appeared to have gone through its certification process. In the Panel's view the TOPCAT briefing document was likely to have gone through Procter & Gamble's certification process given the similarity of its reference code to the reference code on the other two documents.) In its response Sanofi-Aventis submitted documents supplied to customers.

Nonetheless the Panel noted that the Nurse Audits document, the TOPCAT flow chart, the TOPCAT Surgery Nomination Form and TOPCAT Briefing Document were originally provided by the complainant who described himself as a current employee of Sanofi-Aventis. He corresponded with the Authority under a pseudonym. The Panel was thus extremely cautious when deciding what weight to attribute to this evidence. The provision of relevant documents by a current Sanofi-Aventis employee might be seen as inconsistent with the company's comments on the availability of documents. Nonetheless the Panel did not know how or from where the complainant had obtained the documents.

The Panel further noted Sanofi-Aventis' submission that the ABBH was a collaboration between two independent companies and that as such it was likely

that the two had differing involvement and participation in particular initiatives relating to Actonel. The Panel noted, however, that Procter & Gamble had submitted the Programme: Update and Changes to Osteoporosis Review document (ref A2121), which clearly linked the two companies (it was written on notepaper headed with the two company logos) and which in the accompanying Sales Force Call Agenda (June 2003) clearly linked the provision of the nurse audit service to the prescription of Actonel ie call objective was to gain agreement to prescribe Actonel as first choice. The Sales Force Call Agenda referred to completing the booking form with input from 'local Alliance territory team including opposite Alliance RBM/RSM, P&G Account Executive and Aventis Hospital Rheumatology Team'. Weekly update reports would be sent to 'all Alliance RBM/RSMs including approved nominations tracker…'.

The Panel considered that the Programme: Update and Changes to Osteoporosis Review document did not meet the requirements of the Code. Sanofi-Aventis had been provided with a copy of Procter & Gamble's response by Procter and Gamble. The Authority had asked Sanofi-Aventis to comment on any differences. Sanofi-Aventis had not commented on this specific document. The document encouraged representatives to only offer the service to those surgeries which used Actonel as first choice. The Panel noted its comments above on the TOPCAT documents which referred to the ABBH and to Aventis. The Panel considered that the selection of practices for the nurse audit and TOPCAT were unacceptable and this meant that the arrangements were contrary to the requirements of Clause 18.1 and ruled accordingly. This ruling was appealed.

The Panel further considered that the overall arrangements brought discredit upon the pharmaceutical industry; a breach of Clause 2 was ruled. This ruling was appealed.

The Panel decided to report Sanofi-Aventis to the Code of Practice Appeal Board in accordance with Paragraph 8.2 of the 2006 Constitution and Procedure.

With regard to the promotion of Actonel for corticosteroid-induced osteoporosis, the Panel noted that throughout the period of the nurse audit and of TOPCAT, Actonel 5mg was so licensed. Although Actonel 35mg was not licensed for use in corticosteroid-induced osteoporosis, there was no evidence that it had been promoted for such an indication. No breach of Clause 3.1 was ruled.

Case AUTH/1902/10/06

APPEAL BY SANOFI-AVENTIS

Sanofi-Aventis appealed the Panel's rulings of breaches of Clauses 18.1 and 2 of the 2003 Code.

Sanofi-Aventis explained that the programmes offered medical services which were in demand, to assist practices in better identifying patients at risk of osteoporosis and then confirming diagnosis, at a time when the NHS would not have funded such services at all. An independent agency which employed and trained nurses managed both the services and contacts with prescribers, independently of representatives and the ABBH, in accordance with best practice. Practitioners who requested the services were free to prescribe whichever non-medicinal or medicinal treatment they deemed most appropriate for their patient. The arrangements for the programmes did not limit access to doctors who would only prescribe Actonel as their first choice of treatment and did not breach Clause 18.1. The programmes were conducted and completed before the current management of Sanofi-Aventis took over Aventis. The programmes did not and would not bring the industry into disrepute.

Sanofi-Aventis noted that the Panel had ruled a breach of Clause 18.1, as a result of its finding that practices were selected for the nurse audit and TOPCAT programmes on the basis that representatives would only offer the services to those surgeries that agreed to use Actonel first choice/first line. Sanofi-Aventis submitted that the conclusions of the Panel were incorrect because:

- The Panel had relied upon documents that were never used by representatives or to brief representatives during the implementation of the nurse audit or TOPCAT programmes.
- Documentation in relation to the nurse audit programme had been misinterpreted.
- The programmes were not limited to practices who prescribed Actonel as their preferred choice of treatment.
- The data for individual practices did not support a contention that the nurse audit and TOPCAT programmes acted as inducements to prescribe Actonel.
- The nurse audit and TOPCAT programmes must be considered in the context of the 2003 Code.

Sanofi-Aventis submitted that further submissions in relation to these grounds would be provided in advance of the appeal hearing following consideration of preliminary procedural questions by the Chairman.

Sanofi-Aventis submitted that the Panel had provided no reasoning to justify its finding of a breach of Clause 2, simply stating that 'the overall arrangements brought discredit upon the pharmaceutical industry'. The supplementary information to Clause 2 stated 'a ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances'. In this context, fairness required that the Panel should provide reasons explaining its conclusion that the circumstances of this case warranted such censure. Sanofi-Aventis disagreed with the finding of the Panel. Moreover, it was significant that, in reaching its conclusion with respect to Clause 2, the Panel had not mentioned the following three issues which should properly have been considered:

Firstly the very substantial benefits both to patients and to the NHS resulting from the programmes and the fact that participating doctors were clearly free to

prescribe whatever medicine they chose or to prescribe no treatment. Sanofi-Aventis noted a GP's statement that 'this kind of service represents true partnership between the NHS and pharmaceutical industry'. Secondly, the fact that, following the conclusion of the nurse audit and TOPCAT programmes, Sanofi-Aventis and its current directors had no involvement with the matters which were the subject of complaint. And thirdly it was also relevant that the procedures followed by Aventis were modified following the merger. These matters, which were directly relevant to the culpability of the merged company and its current directors, had not seemingly been taken into account by the Panel in considering its ruling in relation to Clause 2.

Sanofi-Aventis took a finding of a breach of Clause 2 extremely seriously and submitted that it should be reserved for cases where it had proper meaning. In circumstances where neither Sanofi-Aventis nor any of the current directors of the company had any involvement in or opportunity to influence the programmes that were the subject of complaint, a finding of a breach of Clause 2 was inappropriate.

Sanofi-Aventis submitted that the ruling of the Panel in relation to Sanofi-Aventis, with respect to the nurse audit and TOPCAT programmes, was incorrect and it requested that the Panel's rulings in respect of breaches of Clauses 18.1 and 2 of the 2003 Code, were set aside by the Appeal Board.

FURTHER SUBMISSION BY SANOFI-AVENTIS

Sanofi-Aventis noted that the programmes at issue were run as services to medicine, by the ABBH which was set up in 1997 in the US and subsequently in the UK by Procter & Gamble and Hoechst Marion Roussel, to share know-how and certain costs (including sales force, promotional and non-promotional services) relating to the marketing of Actonel for the treatment of osteoporosis. In 1999, Hoechst Marion Roussel merged with Rhone Poulenc Rorer to form Aventis. Since that time, the two participants in ABBH in the UK had been Procter & Gamble and Aventis Pharma Limited. During that time Sanofi was the UK subsidiary of Sanofi, an independent pharmaceutical company. It was only in the first quarter of 2005 that Sanofi's operations were merged with those of Aventis.

Sanofi-Aventis noted that in October 2006, the Authority wrote to Sanofi-Aventis, regarding an anonymous complaint received in relation to a nurse audit programme, run by ABBH between 2002 and 2004. The letter from the Authority stated a current employee at Sanofi-Aventis had complained under the Code regarding the ABBH nurse audit programme using a pseudonym. An anonymised copy of the letter of complaint was enclosed with the letter from the Authority, together with various documents provided by the anonymous complainant. (These documents in fact related to two separate audit programmes, the nurse audit programme and TOPCAT which were described below).

The complainant subsequently sent a second letter to the Authority making further allegations in respect of activities by ABBH. The Panel had ruled no breach of the Code regarding these latter allegations.

Investigation of the complaint by Sanofi-Aventis

Sanofi-Aventis submitted that both it and Procter & Gamble experienced substantial difficulties investigating the matters raised by the anonymous complainant as the programmes had been concluded and between 2 and 5 years had elapsed following the matters which were the subject of the complaint.

Sanofi-Aventis submitted that the prejudice resulting from the delay had been heightened as, during the relevant period, the company had undergone substantial changes which affected the availability of documents and evidence from staff. The acquisition of Aventis by Sanofi took place in December 2004, shortly after the relevant programmes were concluded. At the time of the acquisition, many Aventis personnel left the company; in particular, none of the medical or regulatory teams transferred to Sanofi. No member of the current management of Sanofi had worked for Aventis prior to the acquisition or had any involvement in the programmes referenced in the complaint. Furthermore, Aventis documentation and electronic files were lost whilst under Aventis' control.

Sanofi-Aventis submitted that the information available to it in relation to issues raised by the anonymous complainant were therefore incomplete and the company's ability to investigate the allegations raised had been limited as a result of corporate reorganisation, staff departures and changes in management and other personnel.

Programmes referred to in the complaint

Sanofi-Aventis noted that the documentation provided by the anonymous complainant related to two programmes run by the ABBH, a nurse audit and TOPCAT, both of which reflected government policy to improve the diagnosis and management of patients with osteoporosis. The importance of this therapeutic area was emphasised in 1999 in the Secretary of State for Health's White Paper 'Saving Lives: Our Healthier Nation' which highlighted the significance of osteoporosis as a major cause of death and disability in older people. In the National Service Framework for Older People, issued in March 2001, Standard 6 focused on reducing the number of falls which result in serious injury. One of the key aspects of a strategy to reduce injury associated with falls was for GPs to take responsibility for assessing risk of osteoporosis and identifying those who required prevention or treatment. However, despite the importance placed upon the appropriate treatment of patients at risk of osteoporosis, at the time relevant to the complaint, doctors were under-resourced to make such diagnoses. In particular, the availability of dual X-ray absorpiometry (DXA) to measure bone mineral density and predict fracture risk, was severely limited. In the absence of DXA scanning, doctors at that time, were unable to diagnose patients at risk of osteoporosis.

In these circumstances, Sanofi-Aventis submitted that the programmes offered by Aventis and Procter & Gamble provided a valuable service to medicine and the NHS and substantial benefits to patients. In this regard Sanofi-Aventis referred to statements from doctors who reviewed and participated in the programme. Similar services were provided at the time by other companies which supplied treatments for osteoporosis in the UK.

Nurse Audit Programme

The nurse audit programme was run by an independent organisation which specialised in providing audit protocols and reports for general practices. The programme followed a detailed protocol, incorporating best practice guidelines, including Primary Care Rheumatology Guidelines and guidelines issued by the RCP. An explanation of the nurse audit programme was provided in a statement by a Procter & Gamble employee (as provided by Procter & Gamble) supported by an email from a research nurse in clinical gerontology.

Sanofi-Aventis submitted that the programme was run in two phases. During phase 1, patients with established osteoporosis and/or a high risk of fracture (including patients on long term oral steroids, patients with confirmed osteoporosis on calcium supplements alone, patients with radiographic evidence of bone loss or vertebral deformity, etc and patients with a previous fragility fracture) would be assessed by the nurses as requiring immediate treatment. In phase 2, patients with osteoporosis risk factors but with an unconfirmed diagnosis, would be invited for DXA scanning and consultation with nurses. Following the review, the nurse would provide the GP with a final report collated from the records and patient reviews. The GP would then decide which treatment, if any, should be offered to patients with osteoporosis.

Representatives employed by ABBH partners were not involved in the programme and did not have access to any materials arising from it. Representatives discussed the existence of the programme with practices in non-promotional calls. The nurse audit programme commenced as a pilot service in late 2001 and was discontinued on 31 October 2004.

TOPCAT

Sanofi-Aventis submitted that the TOPCAT programme also aimed to assist GPs to identify patients at risk of osteoporosis, but used software rather than nurses to analyse patients' records. The programme was applied by the GP or by an independent organisation. An explanation of the TOPCAT programme was provided in the statement of a Procter & Gamble employee (as provided by Procter & Gamble).

Sanofi-Aventis submitted that the third party staff or the GP would use the TOPCAT software to identify patients at risk of osteoporosis. A patient so identified would be reviewed by the GP who would agree a management strategy for that patient, which might include further investigation or clinical review, advice regarding smoking cessation, prescription of vitamin D or other osteoporosis treatments.

Sanofi-Aventis submitted that again, the involvement of ABBH representatives was limited to an initial discussion, during the course of a non-promotional visit, regarding the availability of the service. At no time did any employee of ABBH companies have access to information about patients, nor any participation in any subsequent prescribing decision by the GP.

Grounds for appeal

Sanofi-Aventis submitted that a feature of this complaint was the fact that the name of the complainant was not made known to the Authority, which was provided only with a pseudonym. Whilst the complainant claimed to be a current employee of Sanofi-Aventis, although one who did not work in the osteoporosis part of the business, it was unclear whether the Authority had been able to confirm these details, or the source of the documents provided by the complainant in relation to the nurse audit and TOPCAT programmes. Furthermore, the Panel had seemingly relied upon the unsubstantiated evidence of the anonymous complainant in the following respects:

- In concluding that documents provided by the complainant, specifically the Nurse Audits document (ref CP&S UK MDO) and the TOPCAT Briefing Document (ref ACT8070904), the flowchart for selection of TOPCAT surgeries (ref ACT7330504 A2541) and the TOPCAT Surgery Nomination Form (ref ACT7330504 A2541) were used to brief representatives in relation to the nurse audit or TOPCAT programmes. The explanations provided by Sanofi-Aventis and Procter & Gamble, as to why they considered such documents were not used to implement the programmes, had not been addressed by the Panel.

- In suggesting that the disclosure provided by Sanofi-Aventis had been incomplete, the Panel had seemingly relied upon the assertion of the complainant that he was a current employee of Sanofi-Aventis and the fact that he provided documentation, which he claimed was used in implementing the programmes, that could not be located by the company.

The explanations provided by Sanofi-Aventis were supported by evidence:

- Witnesses (including a Procter & Gamble employee who contributed to the development of the nurse audit programme; another Procter & Gamble employee who was involved in the running of the TOPCAT programme; doctors who reviewed and participated in the programmes; and a technician who carried out DXA scanning as part of the nurse audit).

- Sales IMS data confirming the prescribing patterns of the practices which participated in the programmes.

- The explanations of the companies as to how the documents relied upon by the Panel should properly be interpreted.

In the context of this evidence, Sanofi-Aventis submitted that it was simply not open to the Panel to rely upon unsubstantiated inference based on an anonymous complaint that might not be tested through cross-examination. Sanofi-Aventis provided an opinion from a Queen's Counsel (QC).

Sanofi-Aventis submitted that the Panel made various assertions which were unreasoned and unclear. Sanofi-Aventis had requested that sufficient explanations and/or reasons be provided in advance of the appeal hearing so that the company might consider the basis for the decision of the Panel and appropriately prepare its submissions for the appeal. However, the information requested had not been made available to the company.

Sanofi-Aventis noted that the Panel had ruled a breach of Clause 18.1 of the Code by both it and Procter & Gamble as a result of the findings that the selection of practices for the nurse audit and TOPCAT programmes indicated that 'representatives would only offer the services to those surgeries that agreed to use Actonel first choice/first line'.

Sanofi-Aventis submitted that the Panel had confirmed that the documents given to doctors in respect of the nurse audit and TOPCAT programmes did not refer to Actonel and were not objectionable. However, the Panel seemingly failed to recognise the very substantial benefits gained by patients and by the NHS as a result of the nurse audit and TOPCAT programmes. These benefits were clear from the statement of the Chairman of the National Osteoporosis Society Primary Care Forum who assisted in the development of the programmes. His statement confirmed, 'the audit service provided by ABBH has assisted practices to identify patients at risk of osteoporosis using [guidelines from the RCP and NICE]. The independent nurses and DXA scanning services have helped overcome the capacity issues facing the NHS'. Other doctors who participated in the programmes had also confirmed their views.

Sanofi-Aventis submitted that in reaching its conclusions with respect to Clause 18.1, the Panel relied on various documents provided by the complainant or disclosed by Procter & Gamble. None of these documents were located by Sanofi-Aventis and the current management of the company had no direct knowledge of them. Furthermore, reliance on these documents and their interpretation by the Panel was inappropriate for the following reasons:

Sanofi-Aventis submitted that the Nurse Audits document (Ref CP&S UK MDO) was seemingly generated by Procter & Gamble in May 2004. A copy of the document was found by Procter & Gamble in a file containing draft documents and final material used for a sales conference in May 2004, although it did not appear that the document was used at the conference. In the context of the reference at the bottom of the document which indicated that it was created for the UK head office based commercial team - Customer Planning and Strategy, Procter & Gamble submitted that the document was used only for internal purposes at its head office (specifically to obtain the support of management to the continuation of the programme). In May 2004, the person responsible for the nurse audit programme at Procter & Gamble no longer worked with the company. He was, at that time, subject to a performance review and his work was closely supervised. Any documents generated by him that were intended to be released to the sales force would have been first reviewed by his line manager who had confirmed that, prior to this investigation, she had not seen the nurse audit document. This evidence strongly suggested that the document was used only for internal purposes. Moreover there was no positive evidence that this document was used to brief representatives.

Sanofi-Aventis submitted that while the anonymous complainant had produced various documents in relation to the TOPCAT programme (a TOPCAT Briefing Document, a Flowchart for Selection of TOPCAT Surgeries and a TOPCAT Surgery Nomination Form) from an unidentified source, there was no evidence that any of this material was ever used to brief representatives or otherwise in implementing the programme.

Sanofi-Aventis submitted that the Programme: Update and Changes to Osteoporosis Review document, was located by Procter & Gamble amongst its documents. In its decision, the Panel referred to the sentence in that document which stated that 'assessment of the surgeries already reviewed showed there to be an increased proportion of patients already receiving bisphosphonate treatment compared to the pilot. This reduced the number of patients in each surgery that could benefit from the review. Therefore the quality of nominations needed to improve'. The Panel did not explain the apparently adverse inference it had drawn from this wording and Sanofi-Aventis was therefore prejudiced in its ability to respond. However, while Sanofi-Aventis had no direct knowledge of this document, in circumstances where the aim of the nurse audit programme was to identify and investigate women at risk of osteoporosis, where the diagnosis was unrecognised, it was self-evident that an increase in the proportion of patients taking bisphosphonates would indicate a higher proportion of patients already reviewed by the GP and a smaller number who would therefore benefit from the audit. In the context of a limited budget it was clearly appropriate for the programme to be directed towards practices where the greatest number of patients might benefit and, in these circumstances, no adverse inferences should be drawn from the wording of the document. Sanofi-Aventis referred to the background information provided by a Procter & Gamble employee which stated:

'While I was not involved in the preparation of the [Programme: Update and Change to Osteoporosis Review] dated June 2003, a further document provided to the PMCPA by Procter & Gamble Pharmaceuticals, I am aware of the history behind its content. Following the pilot

Programme we assessed the efficiency of the arrangements. At this stage it became clear that the costs incurred in providing the audit service were much higher per patient with surgeries which had small list sizes. This was because there were fixed costs associated with audit which were the same whatever the size of the practice; e.g. introductory meeting (1 day), final presentation of the results to the practice (1 day) and the use of the DXA scanner (where costs were the same whether 4 patients or 14 patients were scanned in a day). Additionally small surgeries tended not to have a practice manager and were not fully Read Coded; therefore note searching in these practices was slow and inefficient. Accordingly, we made a decision to concentrate the programme on practices with larger patient lists where more patients could benefit within our budget.'

Sanofi-Aventis noted that the Panel subsequently referred to the Sales Force Call Agenda (June 2003) also located by Procter & Gamble and disclosed to the Authority. The Panel asserted that this document 'clearly linked the offer of the service to those practices who agreed to prescribe Actonel first choice'. This interpretation of the document was incorrect. The agenda envisaged that a sales call would be undertaken where the objective was to 'gain agreement to prescribe Actonel as first choice therapy…'. However, there was no link in the document between that sales call and the subsequent assessment of suitability for osteoporosis review. The list of factors to be considered in relation to the assessment of suitability for participation in the nurse audit, as set out in the agenda, did not include any requirement that the practice had in fact agreed to prescribe Actonel as first choice therapy or at all. Furthermore, it was significant that the Osteoporosis Surgery Booking Form also provided to the Authority included no requirement that the practice had agreed to prescribe Actonel first line. Sanofi-Aventis submitted that in these circumstances the inferences drawn from the documents by the Panel were unfair.

Sanofi-Aventis submitted that the Panel had been wrong to conclude that the nurse audit and TOPCAT programmes were offered only to those surgeries that agreed to use Actonel first line. In fact, practices which did not prescribe Actonel first line were also nominated and did participate in the programmes. In its defence, Sanofi-Aventis provided the Authority with a statement from a doctor who confirmed that this was the case and this had been reiterated by that doctor and by other doctors who participated in the programme.

Furthermore, Sanofi-Aventis had seen data obtained by Procter & Gamble in relation to the prescription of bisphosphonates by practices who participated in the nurse audit programme. This data provided definitive proof that ABBH did not limit participation to practices where Actonel was prescribed first line. The data confirmed that in a significant proportion of the practices, Actonel prescriptions comprised only a tiny percentage of the number of bisphosphonate prescriptions issued and in a number of practices which participated, Actonel was not prescribed at all.

Sanofi-Aventis provided two graphs showing the share of the bisphosphonate market attributable to Actonel in each of the practices which participated in the nurse audit programme. Between January and June 2002, the graph indicated that none of the practices which participated used Actonel first line. The graph covering the period between July and December 2004 indicated that whilst Actonel's market share had increased from 2002, it still remained the position that approximately one third of practices which participated in the nurse audit programme, prescribed Actonel at a rate lower than the national average.

Sanofi-Aventis submitted that in view of the fact that doctors could be supplied with TOPCAT to implement themselves, it was not possible to obtain and interpret sales data over a period in a similar way for TOPCAT. However, sales data obtained by Procter & Gamble confirmed that TOPCAT was not offered only to practices that prescribed Actonel first line and that the share of bisphosphonate market attributable to Actonel in participating practices was broadly in line with the national market share.

Sanofi-Aventis submitted that these data clearly demonstrated that neither the nurse audit programme nor the TOPCAT programme imposed a requirement that Actonel should be prescribed first line before practices could be nominated for inclusion.

Sanofi-Aventis noted that the Panel had relied upon data obtained by Procter & Gamble, which showed that 88% of treated patients were initiated on Actonel in the nurse audit programme between March 2003 and October 2004 (and that approximately 60 patients were started on Actonel as a result of TOPCAT in 2004), in reaching its conclusion that the programmes did not meet the requirements of Clause 18.1 of the 2003 Code.

Sanofi-Aventis submitted that the 88% figure referred to in Procter & Gamble's response was not credible. The data which formed the basis for this figure had not been shown to Sanofi-Aventis and was not now available to Procter & Gamble; it was wholly inconsistent with sales data. In these circumstances and in the context of the sales data, the figure of 88% was more likely to refer to the number of patients prescribed a bisphosphonate, following the nurse audit rather than the number prescribed Actonel.

Sanofi-Aventis submitted that in addition, during the TOPCAT programme, 2,956 patients were identified as being at risk of osteoporosis in 2004 and of these only approximately 60 patients (some 2.3%) were prescribed Actonel. While it was unclear what percentage of patients were prescribed any treatment, on no view did a prescribing rate of 2.3% of patients identified to be at risk of osteoporosis suggest that the TOPCAT surgeries were selected on the basis that Actonel would be prescribed first line or that participation in the programme constituted an inducement to prescribe contrary to Clause 18.1. Indeed, the data suggested the opposite.

Sanofi-Aventis submitted that statements from individual doctors involved with the programme

confirmed that the offer was not linked to prescribing of Actonel. Moreover, while one of the doctors was unable, as a result of the passage of time, to remember details of the programme, data confirmed that the rates of prescribing at his surgery remained broadly the same throughout the period when the nurse audit was conducted. Jan - June 2002: 16%; July - Dec 2002: 9%; Jan - June 2003: 15%; July - Dec 2003: 22%; and July - Dec 2004: 17%. In these circumstances, it was clear, contrary to the conclusions of the Panel, that the nurse audit and TOPCAT programmes did not act as an inducement to prescribe Actonel.

Sanofi-Aventis submitted that while the evidence demonstrated clearly that practices were not selected for inclusion in the nurse audit and TOPCAT programmes only if they were willing to prescribe Actonel, even if the Appeal Board was to make a contrary finding it did not of itself constitute a breach of Clause 18.1 of the 2003 Code.

Sanofi-Aventis noted that supplementary information to Clause 18.1 of the 2003 Code stated that this 'does not prevent the provision of medical and educational goods and services which will enhance patient care or benefit the National Health Service'. Such services were welcomed by the Government and by the NHS and the Panel did not suggest they were objectionable. It was absolutely clear that the nurse audit and TOPCAT programmes provided a valuable service to the NHS in circumstances where the resources to identify patients at risk of osteoporosis, through DXA scanning, were limited and that patients derived substantial benefit from these programmes. However, it was self-evident that services to medicine would not be provided by companies if the result was to benefit their competitors at their own expense. The result of the Panel's approach was that such programmes would be offered only by companies whose products had a majority market share, where the programme would not advantage their competitors. This was clearly undesirable.

Sanofi-Aventis noted the supplementary information to Clause 18.1 of the 2003 Code stated 'the provision of such goods or services must not be done in such a way as to be an inducement to prescribe, supply, administer, recommend or buy any medicine…'. Extensive guidance was provided to assist companies in relation to medical and educational goods and services. It was noteworthy that at no place did the Code or its supplementary information suggest that the provision of medical goods and services might not be made available to practices that already prescribed a company's products, in circumstances where the doctor was free to prescribe any medication or no medication, as he saw fit. The revisions to the Code introduced in 2006 included no such wording.

Sanofi-Aventis submitted that if, in the circumstances described above, the Authority believed that services to medicine offered by a company to practices which prescribed or who were willing to consider prescribing that company's products, constituted a breach of Clause 18.1 of the Code, this view should be clearly stated in the supplementary information. In the absence of any guidance indicating that such arrangements were objectionable, it was unfair for the Panel to give a ruling adverse to Procter & Gamble and Sanofi-Aventis in circumstances where the programmes themselves were valuable and created no obligation for a participating doctor to prescribe Actonel or any medicine.

In summary, Sanofi-Aventis submitted that, the overwhelming weight of the evidence indicated that the nurse audit and TOPCAT programmes were provided as services to medicine, to fulfil clinical need and to benefit patients in the NHS. Practices which did not prescribe Actonel first line were not excluded from the programmes and there was absolutely no evidence that these programmes in any way constituted an inducement to prescribe, contrary to Clause 18.1.

Sanofi-Aventis submitted that a finding of a breach of Clause 18.1 did not necessarily result in a ruling that Clause 2 had been breached. However, in this case, the Panel had provided no reasoning to justify the finding of a breach of Clause 2 in respect of both companies, simply stating that 'the overall arrangements brought discredit upon the pharmaceutical industry'. Sanofi-Aventis emphatically disagreed that this was the case. The supplementary information to Clause 2 stated 'a ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances'. In these circumstances, it was incumbent upon the Panel to provide proper reasons explaining the circumstances of this case that warranted such censure.

Sanofi-Aventis submitted that it was significant that, in reaching its conclusion with respect to Clause 2, the Panel had seemingly failed to take into account the following issues which should properly have been considered:

- The very substantial benefits both to patients and to the NHS resulting from the programmes and the fact that participating doctors were clearly free to prescribe whatever medicine they chose or to prescribe no treatment. In direct contrast to the findings of the Panel, a GP stated 'this kind of service represents true partnership between the NHS and pharmaceutical industry'.

- The fact that the Panel confirmed that the documents given to doctors with respect to the nurse audit and TOPCAT programmes were not objectionable.

- The fact that physicians did not perceive the programmes as inducements to prescribe, statements provided by doctors who participated in the programmes had confirmed that they did not consider the arrangements an inducement to prescribe and that they would not have participated in the programmes had they found any such inducement to be present.

- The fact that, following the conclusion of the nurse audit and TOPCAT programmes, Aventis was acquired by Sanofi, and that Sanofi-Aventis and its current management had no involvement with the matters which were the subject of complaint.

Sanofi-Aventis took a finding of a breach of Clause 2 of the Code extremely seriously, it should be reserved for cases where it had proper meaning. In circumstances where neither Sanofi-Aventis nor any member of the current management of the company had any involvement in or opportunity to influence the programmes that were the subject of complaint, a finding of breach of Clause 2 was inappropriate.

- It was also relevant that the procedures followed by the company underwent substantial revision following the merger and were wholly different from those that were in place at Aventis at the time of the nurse audit and TOPCAT programmes. These matters which were directly relevant to the culpability of the merged company and its current management had not seemingly been taken into account by the Panel in considering its ruling in relation to Clause 2.

Overall, therefore, Sanofi-Aventis submitted that the ruling of the Panel in relation to both it and Procter & Gamble, with respect to the nurse audit and TOPCAT programmes, was unreliable and unfair and it respectfully requested that the Panel's rulings in respect of breaches of Clauses 18.1 and 2 of the 2003 Code be set aside by the Appeal Board.

Case AUTH/1903/10/06

APPEAL BY PROCTER & GAMBLE

Procter & Gamble appealed the Panel's rulings of breaches of Clauses 18.1 and 2 of the 2003 Code.

Procter & Gamble submitted that its reasons for appealing included the following:

- The programmes offered medical services which were in demand, to assist practices in better identifying patients at risk of osteoporosis and then confirming diagnosis, at a time when the NHS would not have funded such services at all.
- An independent agency which employed and trained nurses managed both the services and contacts with prescribers, independently of representatives and the ABBH, in accordance with best practice.
- Practitioners who requested the services were free to prescribe whichever non-medicinal or medicinal treatment they deemed most appropriate for their patients.
- The arrangements for the programmes did not limit access to doctors who would only prescribe Actonel as first choice of treatment and did not breach Clause 18.1.
- The programmes did not and would not bring the industry into disrepute.

With regard to the Panel's ruling of a breach of Clause 18.1, Procter & Gamble submitted that the conclusions of the Panel were incorrect for the following reasons:

The Panel had relied upon documents that were never used by representatives to implement the nurse audit or TOPCAT programmes.

Investigations by Procter & Gamble had indicated that documents disclosed by the complainant and relied upon by the Panel, were only used by head office staff and were not distributed to representatives, who were instead briefed orally in relation to the nomination of practices. The briefing of representatives was conducted in accordance with the flowchart in the document 'Actonel GP Call Agenda and Follow Up November 02 to January 03' which confirmed that any discussion with doctors regarding the nurse audit programme was conducted at a separate visit from any promotion of Actonel.

Furthermore, Procter & Gamble submitted that the inferences drawn by the Panel were inconsistent with the Sales Force Call Agenda which listed the criteria to be taken into account when considering a practice for nomination to the programme; these did not include any requirement that Actonel should be prescribed the first line or at all.

Procter & Gamble had confirmed with representatives and doctors who participated in the nurse audit that (a) representatives did not only nominate practices which prescribed Actonel first line (b) participating doctors felt themselves to be free to prescribe whatever treatment was most appropriate for their patients.

Procter & Gamble submitted that the nurse audit documents had been misinterpreted. The Panel had wrongly assumed that documents for internal commercial purposes were used to brief representatives.

Moreover, certain documents (including the Sales Force Call Agenda) had been misconstrued as indicating that a pre-programme sales visit by representatives was part of the audit programme. As indicated by proper consideration of the document and confirmed by participating doctors, this was not the case; promotional activity by representatives was conducted separately from any discussion regarding the nurse audit.

Procter & Gamble submitted that the programmes were not limited to practices which prescribed Actonel first line. It was clear from the data that participating practices were not limited to those which prescribed Actonel first line.

Procter & Gamble had been able to conduct a comprehensive analysis of the data from 323 of the 351 practices that were involved in the nurse audit programme. In the average practice that participated, Actonel had an initial market share of just 14%. The market share of Actonel across the practices at the beginning of 2002 varied from 0% to 46%. Over one third (38%) of practices that took up the opportunity to be involved in the programme, prescribed Actonel at a rate below its average national share of the bisphosphonate market. These data clearly disproved the allegation that only first line and Actonel friendly practices were offered the nurse audit programme.

Procter & Gamble submitted that the position with respect to TOPCAT was similar. Data previously provided to the Authority showed that, of the patients identified as being at risk of osteoporosis in 2004, only around 2% were prescribed Actonel. Such prescribing rates were well below the national average for the product and again demonstrated conclusively that practices were not selected on the basis that Actonel was the first line bisphosphonate.

Procter & Gamble submitted that the data for individual practices did not support a contention that the nurse audit and TOPCAT programmes acted as an inducement to prescribe Actonel. The data obtained in relation to prescribing by individual practices also demonstrated that the nurse audit programme made little difference in the relative proportion of bisphosphonate prescriptions issued for Actonel. In particular, the proportion of practices which prescribed Actonel at a rate below the national average remained relatively unchanged before and after the programme.

Procter & Gamble submitted that the nurse audit and TOPCAT programmes must be considered in the context of the 2003 Code and industry practice at that time. For the reasons explained above, Procter & Gamble maintained that there was no link between the availability of the nurse audit and TOPCAT programmes and the prescription of Actonel. However, if the Appeal Board believed that it was inappropriate for a company to offer a service to medicine to a practice which might issue some prescriptions in respect of its products, then that fact should be clearly stated in the Code. It was significant that there was no exclusion of such activity in the wording of the 2003 Code and that, when the Code was revised in 2006, no additional guidance was provided in this context.

Further submissions in relation to these grounds would be provided in advance of the appeal hearing.

Procter & Gamble noted that the Panel had provided no reasoning to justify the finding of a breach of Clause 2 in respect of Procter & Gamble, simply stating that 'the overall arrangements brought discredit upon the pharmaceutical industry'. Procter & Gamble disagreed that this was the case. The supplementary information to Clause 2 stated 'a ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances'. In these circumstances, fairness required that the Panel should provide reasons explaining its conclusion that the circumstances of this case warranted such censure.

Procter & Gamble submitted that it was significant that, in reaching its conclusion with respect to Clause 2, the Panel had not mentioned four issues which should properly have been considered:

Firstly, the very substantial benefits both to patients and to the NHS resulting from the programmes. Secondly, participating doctors were clearly free to prescribe whatever medicine they chose or to prescribe no treatment and felt under no pressure to prescribe Actonel. Thirdly, physicians did not perceive the programmes as inducements to prescribe. And fourthly, Clause 18.1 of the 2003 Code had not specifically excluded the offer of a service to medicine to those practices who already prescribed a company's products. (The 2006 version of the Code made no revision to incorporate such a requirement).

Overall, therefore, Procter & Gamble submitted that the ruling of the Panel in relation to Procter & Gamble was incorrect and it respectfully requested that the Panel's rulings of breaches of Clauses 18.1 and 2 of the 2003 Code were set aside by the Appeal Board.

FURTHER SUBMISSION BY PROCTER & GAMBLE

Procter & Gamble submitted that the programmes that were the subject of complaint were run as services to medicine by ABBH which was set up in 1997 in the US and subsequently in the UK by Procter & Gamble and Hoechst Marion Roussel, to share know-how and certain costs including sales force, promotional and non-promotional services relating to the marketing of Actonel for the treatment of osteoporosis. In 1999, Hoechst Marion Roussel merged with Rhone Poulenc Rorer to form Aventis. Since that time, the two participants in ABBH in the UK had been Procter & Gamble Pharmaceuticals and Aventis Pharma Limited. During that time Sanofi-Synthelabo Limited was the UK subsidiary of Sanofi-Synthelabo, an independent pharmaceutical company. It was only in the first quarter of 2005 that Sanofi-Synthelabo's operations were merged with those of Aventis.

In October 2006, the Authority wrote to Procter & Gamble, regarding an anonymous complaint received in relation to a nurse audit programme, run by ABBH between 2002 and 2004. The letter from the Authority stated a current employee at Sanofi-Aventis had complained under the Code regarding the ABBH nurse audit programme using a pseudonym. An anonymised copy of the letter of complaint was enclosed with the letter from the Authority, together with various documents provided by the anonymous complainant. (These documents in fact related to two separate audit programmes, the nurse audit programme and TOPCAT, which were described below).

Procter & Gamble noted that the complainant subsequently sent a second letter to the Authority making further allegations in respect of activities by ABBH. The Panel had ruled no breach of the Code regarding these latter allegations.

Investigation of the complaint by Procter & Gamble

Procter & Gamble stated that both it and Sanofi-Aventis experienced substantial difficulties investigating the matters raised by the anonymous complainant as the programmes had concluded and between 2 and 5 years had elapsed following the matters which were the subject of the complaint and some 2 years since the conclusion of the programmes referred to. During this period, staff at the company had changed and many of the people who participated in the programme were no longer with the company. Furthermore, a fire had taken place at the company's archive in July 2006 and substantial quantities of the

company's documents were destroyed. The information available to Procter & Gamble in relation to issues raised by the anonymous complainant had therefore been incomplete and the company's ability to investigate the allegations raised had been limited as a result of staff departures and the loss of documentation as a result of events outside the control of the company.

Procter & Gamble noted that the documentation provided by the anonymous complainant related to two programmes run by the ABBH; a nurse audit programme and TOPCAT, both of which reflected government policy to improve the diagnosis and management of patients with osteoporosis. The importance of this therapeutic area was emphasised in 1999 in the Secretary of State for Health's White Paper 'Saving Lives: Our Healthier Nation' which highlighted the significance of osteoporosis as a major cause of death and disability in older people. In the National Service Framework for Older People, issued in March 2001, Standard 6 focused on reducing the number of falls which resulted in serious injury. One of the key aspects of a strategy to reduce injury associated with falls was for GPs to take responsibility for assessing risk of osteoporosis and identifying those who required prevention or treatment. However, despite the importance placed upon the appropriate treatment of patients at risk of osteoporosis, at the time relevant to the complaint, doctors were under-resourced to make such diagnoses. In particular, the availability of DXA to measure bone mineral density and predict fracture risk, was severely limited. In the absence of DXA scanning, doctors at that time, were unable to diagnose patients at risk of osteoporosis.

In these circumstances, the programmes offered by Procter & Gamble and Sanofi-Aventis provided a valuable service to medicine and the NHS and substantial benefits to patients. In this regard Procter & Gamble referred to the statement of a GP and other doctors who participated in the programme. Similar services were provided at the time by other companies which supplied treatments for osteoporosis in the UK.

Nurse audit programme

As indicated above, Procter & Gamble submitted that the nurse audit programme was run by an independent organisation which specialised in providing audit protocols and reports for general practices. The programme followed a detailed protocol, incorporating best practice guidelines, including Primary Care Rheumatology guidelines and guidelines issued by the RCP. An explanation of the nurse audit programme was provided in the statement from a Procter & Gamble employee and supported by the email from a research nurse in clinical gerontology.

Procter & Gamble submitted that the programme was run in two phases. During phase 1, patients with established osteoporosis and/or a high risk of fracture (including patients on long term oral steroids, patients with confirmed osteoporosis on calcium supplements alone, patients with radiographic evidence of bone loss or vertebral deformity, etc and patients with a previous fragility fracture) would be assessed by the nurses as requiring immediate treatment. In phase 2, patients with osteoporosis risk factors but with an unconfirmed diagnosis, would be invited for DXA scanning and consultation with nurses. Following the review, the nurse would provide the GP with a final report of information collated from the records and patient reviews. The GP would then decide which treatment, if any, should be offered to patients with osteoporosis.

Procter & Gamble submitted that the involvement of ABBH representatives was limited to an initial discussion regarding the availability of the service in a non-promotional call to practices. This non-promotional call was preceded by and wholly separate from a standard promotional visit, at which representatives would seek to sell Actonel in the usual way. The nurse audit programme commenced as a pilot service in late 2001 and was discontinued on 31 October 2004.

TOPCAT

Procter & Gamble submitted that the TOPCAT programme also aimed to assist GPs to identify patients at risk of osteoporosis, but used software rather than nurses to analyse patients' records. The programme was applied by the GP or by an independent organisation. An explanation of the TOPCAT programme was provided in the statement of another Procter & Gamble employee.

Procter & Gamble submitted that the third party staff or the GP would use the TOPCAT software to identify patients at risk of osteoporosis. A patient so identified would be reviewed by the GP who would agree a management strategy for that patient, which might include further investigation or clinical review, advice regarding smoking cessation, prescription of vitamin D or other osteoporosis treatments.

Again, the involvement of ABBH representatives was limited to an initial discussion, during the course of a non-promotional visit, regarding the availability of the service.

Grounds for appeal

Procter & Gamble submitted that a feature of this complaint was the fact that the name of the complainant was not made known to the Authority, which was provided only with a pseudonym. While the complainant claimed to be a current employee of Sanofi-Aventis, although one who did not work in the osteoporosis part of the business, it was unclear whether the Authority had been able to confirm these details, or the source of the documents provided by the complainant in relation to the ABBH Nurse Audit and TOPCAT programmes.

Procter & Gamble submitted that furthermore, the Panel had seemingly relied upon the unsubstantiated evidence of the anonymous complainant in concluding that documents provided by the complainant, specifically the Nurse Audits document (ref CP&S UK MDO) and the TOPCAT Briefing Document (ref ACT8070904), the flowchart for selection of TOPCAT

surgeries (ref ACT7330504 A2541) and the TOPCAT Surgery Nomination Form (ref ACT7330504 A2541) were used to brief representatives in relation to the nurse audit or TOPCAT programmes. The explanations provided by Procter & Gamble and Sanofi-Aventis, as to why they believed such documents were not used to implement the programmes, had not been addressed by the Panel.

Procter & Gamble submitted that the explanations it provided were supported by evidence:

- Witnesses (including a Procter & Gamble employee who contributed to the development of the nurse audit programme; a Procter & Gamble employee who was involved in the running of the TOPCAT programme; doctors who reviewed and participated in the programmes; and a technician who carried out DXA scanning as part of the nurse audit).

- Sales data confirming the prescribing patterns of the practices which participated in the programmes.

- The explanations of the companies as to how the documents relied upon by the Panel should properly be interpreted.

In the context of this evidence, Procter & Gamble submitted that it was simply not open to the Panel to rely upon unsubstantiated inference based on an anonymous complaint that might not be tested through cross examination. Procter & Gamble provided an opinion from a QC in relation to these issues.

Procter & Gamble submitted that the Panel made various assertions which were unreasoned and unclear. Procter & Gamble had requested that proper explanations and/or reasons be provided in advance of the appeal hearing so that the company might consider the basis for the decision of the Panel and appropriately prepare its submissions for the appeal. However, the information requested had not yet been made available to the company.

Procter & Gamble noted that the Panel ruled a breach of Clause 18.1 by both Procter & Gamble and Sanofi-Aventis as a result of the findings that the selection of practices for the nurse audit and TOPCAT programmes indicated that 'representatives would only offer the services to those surgeries that agreed to use Actonel first choice/first line'. The Panel confirmed that the documents given to doctors in respect of the nurse audit and TOPCAT programmes did not refer to Actonel and were not objectionable. However, the Panel seemingly failed to recognise the very substantial benefits gained by patients and by the NHS as a result of the nurse audit and TOPCAT programmes. These benefits were clear from the statement by the Chairman of the National Osteoporosis Society Primary Care Forum who assisted in the development of the programmes that 'the audit service provided by ABBH has assisted practices to identify patients at risk of osteoporosis using [guidelines from the RCP and NICE]. The independent nurses and DXA scanning services have helped overcome the capacity issues facing the NHS'. This view was supported by the statements of the other doctors and of the technician who carried out the DXA scanning.

Procter & Gamble submitted that in reaching its conclusions with respect to Clause 18.1, the Panel relied on various documents provided by the complainant or disclosed by Procter & Gamble. However, reliance on these documents and their interpretation by the Panel was inappropriate.

Procter & Gamble submitted that the Nurse Audit document (ref CP&S UK MDO) was seemingly generated by Procter & Gamble in May 2004. A copy of the document was found by Procter & Gamble in a file containing draft documents and final material used for a sales conference in May 2004, although it did not appear that the document was used at the conference. In the context of the reference at the bottom of the document which indicated that it was created for the UK head office based commercial team - Customer Planning and Strategy, Procter & Gamble submitted that the document was used only for internal purposes at its head office (specifically to obtain the support of management to the continuation of the programme). In May 2004, the person responsible for the nurse audit programme at Procter & Gamble was no longer with the company. He was, at that time, subject to a performance review and his work was closely supervised. Any documents generated by him that was intended to be released to the sales force was first reviewed by his line manager who had confirmed that, prior to this investigation, she had not seen the Nurse Audit document. This evidence strongly suggested that the document was used only for internal purposes. Moreover there was no positive evidence that this document was used to brief representatives.

Procter & Gamble submitted that whilst the anonymous complainant had produced various documents in relation to the TOPCAT programme (a TOPCAT Briefing Document, a Flowchart for Selection of TOPCAT Surgeries and a TOPCAT Surgery Nomination Form) from an unidentified source, there was no evidence that any of this material was ever used to brief representatives or otherwise in implementing the programme.

Procter & Gamble submitted that the Panel had noted that it had provided no comments in relation to the TOPCAT Briefing Document (ACT 8070904), apparently supplied by the anonymous complainant. This was because the briefing document was not received by the team drafting the response. The reference on the document suggested that it was authorised by Aventis. Procter & Gamble had been unable to locate a copy among its records; it was therefore likely that any copy held by Procter & Gamble was destroyed in the fire. The document appeared to appropriately position the programme apart from the reference to 'Actonel First Line' which, as explained elsewhere, was inconsistent with the way the programme could be or was, in fact, run.

Procter & Gamble submitted that it had found the Programme: Update and Changes to Osteoporosis Review' document among its documents. In its ruling,

the Panel referred to the sentence in that document that 'assessment of the surgeries already reviewed showed there to be an increased proportion of patients already receiving bisphosphonate treatment compared to the pilot. This reduced the number of patients in each surgery that could benefit from the review. Therefore the quality of nominations needed to improve'. The Panel did not explain the apparently adverse inference it had drawn from this wording and Procter & Gamble was therefore prejudiced in its ability to respond. However, in circumstances where the aim of the nurse audit programme was to identify and investigate women at risk of osteoporosis, where the diagnosis was unrecognised, it was self evident that an increase in the proportion of patients taking bisphosphonates would indicate a higher proportion of patients already reviewed by the GP and a smaller number who would therefore benefit from the audit. In the context of a limited budget it was clearly appropriate for the programme to be directed towards practices where the greatest number of patients might benefit and, in these circumstances, no adverse inferences should be drawn from the wording of the document. Procter & Gamble referred to the background information to this document provided by the statement of one of its employees.

Procter & Gamble noted that the Panel subsequently referred to the 'Sales Force Call Agenda' (June 2003) also located by Procter & Gamble. The Panel asserted that this document 'clearly linked the offer of the service to those practices who agreed to prescribe Actonel first choice'. This interpretation of the document was incorrect. The agenda envisaged that a sales call would be undertaken where the objective was to 'gain agreement to prescribe Actonel as first choice therapy…'. However, there was no link made in the agenda between that sales call and the subsequent assessment of suitability for osteoporosis review. The list of factors to be considered in relation to the assessment of suitability for participation in the nurse audit, as set out in the agenda, did not include any requirement that the practice had in fact agreed to prescribe Actonel as first choice therapy or at all. Furthermore, it was significant that the Osteoporosis Surgery Booking Form also provided to the Authority included no requirement that the practice had agreed to prescribe Actonel first line. In these circumstances, Procter & Gamble submitted that the inferences drawn from the documents by the Panel were unfair.

Procter & Gamble submitted that the Panel had been wrong to conclude that the nurse audit and TOPCAT programmes were offered only to those surgeries that agreed to use Actonel first line. In fact, practices which did not prescribe Actonel first line were also nominated and did participate in the programmes. Sanofi-Aventis had provided the Authority with a statement from a GP who confirmed that this was the case and this had been reiterated by that GP and by other doctors who participated in the programme .

Furthermore, Procter & Gamble had obtained data in relation to the prescription of bisphosphonates by practices which participated in the nurse audit programme. Procter & Gamble's submission regarding this data was similar to Sanofi-Aventis.

Procter & Gamble submitted that data clearly demonstrated that neither the nurse audit programme nor the TOPCAT programme imposed a requirement that Actonel should be prescribed first line before practices could be nominated for inclusion. The data for individual practices did not support a contention that the nurse audit and TOPCAT programmes acted as an inducement to prescribe Actonel. The Panel had relied upon data provided by Procter & Gamble, which showed that 88% of treated patients were initiated on Actonel in the nurse audit programme between March 2003 and October 2004 and that approximately 60 patients were started on Actonel as a result of TOPCAT in 2004, in reaching its conclusion that the programmes did not meet the requirements of Clause 18.1 of the 2003 Code.

Procter & Gamble submitted that firstly, the 88% figure previously referred to was not credible. The data which formed the basis for this figure was not available to Procter & Gamble and it was wholly inconsistent with the sales data. In these circumstances and in the context of the sales data, the figure of 88% was more likely to refer to the number of patients prescribed a bisphosphonate, rather than the number prescribed Actonel.

Procter & Gamble submitted that the nurse audit and TOPCAT programmes must be considered in the context of the 2003 Code. While the evidence demonstrated clearly that practices were not selected for inclusion in the nurse audit and TOPCAT programmes only if they were willing to prescribe Actonel, even if the Appeal Board were to make a contrary finding, Procter & Gamble and Sanofi-Aventis submitted that this did not constitute a breach of Clause 18.1 of the 2003 Code.

Procter & Gamble noted that the supplementary information to Clause 18.1 of the 2003 Code stated that this 'does not prevent the provision of medical and educational goods and services which will enhance patient care or benefit the National Health Service'. Such services were welcomed by the Government and by the NHS and the Panel did not suggest they were objectionable. It was quite clear that the nurse audit and TOPCAT programmes provided a valuable service to the NHS in circumstances where the resources to identify patients at risk of osteoporosis, through DXA scanning, were limited and that patients derived substantial benefit from these programmes. However, it was self evident that services to medicine would not be provided by companies if the result was to benefit their competitors at their own expense. The result of the Panel's approach was that such programmes would be offered only by companies whose products had a majority market share, where the programme would not advantage their competitors. This was clearly undesirable.

Procter & Gamble noted that the supplementary information to Clause 18.1 of the 2003 Code went on to state 'the provision of such goods or services must not be done in such a way as to be an inducement to

prescribe, supply, administer, recommend or buy any medicine…'. Extensive guidance was provided to assist companies in relation to medical and educational goods and services. It was noteworthy that at no place did the Code or its supplementary information suggest that the provision of medical goods and services might not be made available to practices that already prescribed a company's products, in circumstances where the doctor was free to prescribe any medication or no medication, as he saw fit. The revisions to the Code introduced in 2006 included no such wording.

Procter & Gamble submitted that if, in the circumstances described above, the Authority considered that services to medicine offered by a company to practices who were willing to consider prescribing that company's products, constituted a breach of Clause 18.1, this view should be clearly stated in the supplementary information. In the absence of any guidance indicating that such arrangements were objectionable it was unfair for the Panel to give a ruling adverse to Procter & Gamble and Sanofi-Aventis in circumstances where the programmes themselves were valuable and created no obligations for a participating doctor to prescribe Actonel or any medicine.

In summary Procter & Gamble submitted therefore the overwhelming weight of the evidence indicated that the nurse audit and TOPCAT programmes were provided as services to medicine, to fulfil clinical need and to benefit patients in the NHS. Practices which did not prescribe Actonel first line were not excluded from the programmes and there was absolutely no evidence that these programmes in any way constituted an inducement to prescribe, contrary to Clause 18.1.

Procter & Gamble submitted that a finding of a breach of Clause 18.1 did not necessarily result in a ruling of a breach of Clause 2. However, in this case, the Panel had provided no reasoning to justify the finding of a breach of Clause 2 in respect of both companies, simply stating that 'the overall arrangements brought discredit upon the pharmaceutical industry'. Procter & Gamble emphatically disagreed that this was the case. The supplementary information to Clause 2 stated 'a ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances'. In these circumstances, it was incumbent upon the Panel to provide proper reasons explaining the circumstances of this case that warranted such censure.

Procter & Gamble submitted that it was significant that, in reaching its conclusion with respect to Clause 2, the Panel had seemingly failed to take into account the following issues which should properly have been considered:

- The very substantial benefits both to patients and to the NHS resulting from the programmes and the fact that participating doctors were clearly free to prescribe whatever medicine they chose or to prescribe no treatment. In direct contrast to the conclusion of the Panel, a GP stated 'this kind of service represents true partnership between the NHS and pharmaceutical industry'.

- The fact that the Panel confirmed that the documents given to doctors with respect to the nurse audit and TOPCAT programmes were not objectionable.

- The fact that physicians did not perceive the programmes as inducements to prescribe. Statements provided by doctors who participated in the programmes had confirmed that they did not consider the arrangements an inducement to prescribe and that they would not have participated in the programme had they found any such inducement to be present.

- Clause 18.1 of the 2003 Code did not specifically exclude the offer of a service to medicine to those practices which already prescribed a company's products. (The 2006 version of the Code made no revision to incorporate such a requirement).

Overall, therefore, Procter & Gamble submitted that the ruling of the Panel in relation to both Procter & Gamble and Sanofi-Aventis, with respect to the nurse audit and TOPCAT programmes, was unreliable and unfair and it respectfully requested that the Panel's rulings in respect of breaches of Clauses 18.1 and 2 of the 2003 Code, were set aside by the Appeal Board.

Cases AUTH/1902/10/06 and AUTH/1903/10/06

COMMENTS FROM THE COMPLAINANT ON THE INITIAL SUBMISSIONS BY THE RESPONDENTS

The complainant noted that both companies stated their reasons for appeal as that the programmes offered much needed services to the NHS which otherwise would not be available. The complainant stated that this might or might not be true dependent on the locality served, however, in general access to NHS diagnostic services in osteoporosis was limited at the time of the programmes.

The complainant noted that an independent agency supplied and oversaw the audit and patient contact undertaken by nurses working to accepted professional standards. However, the complainant's view was that practices were selected by representatives on the basis of prescribing behaviour.

The complainant noted that practitioners were free to prescribe whatever they choose. The complainant alleged that the practices were selected on the basis that Actonel was their medicine of choice, accordingly, the GPs were at liberty to prescribe their medicine of choice ie Actonel, as borne out by 88% of bisphosphonate patients treated as a result of the nurse audit programme being treated with Actonel (data supplied to the Authority by the ABBH).

The complainant alleged that the documents provided with his complaint demonstrated that the programmes did breach Clause 18.1.

The complainant noted that Clause 2 breaches as a result of very similar breaches of Clause 18.1 as

reported in the November 2006 Code of Practice Review were ruled against two other major pharmaceutical companies for practically identical issues with sponsored patient identification programmes. Accordingly, if the Authority was to issue consistent rulings and subsequent sanctions then the current cases must represent a breach of Clause 2 and had unquestionably brought discredit upon the industry.

With regard to Sanofi-Aventis' submission that its current senior management team was not responsible for the conduct of these programmes, the complainant stated that this case was not being brought against individuals but against companies. Sanofi-Aventis represented the merger of Sanofi and Aventis and therefore must be held to account for this behaviour. If not, did a merger provide a means of terminating responsibility for inappropriate behaviour of legacy companies? Furthermore, it should be self-evident that employees responsible for implementing these programmes in a non-Code compliant fashion remained current employees of Sanofi-Aventis. Therefore, their current employer must be held to account for those historical transgressions.

The complainant was stunned and profoundly disappointed at the respondents' denials in this matter. It was utterly self-evident that the Nurse Audits document (ref CP&S UK MDO) document and the TOPCAT flowchart, Surgery Nomination Form and Briefing Document were all intended for a target audience of representatives. To state otherwise defied logic and was a truly pathetic attempt to deny the lack of Code compliance of these programmes. The complainant reminded the Appeal Board of the following:

Nurse Audits document (ref CP&S UK MDO):

- Objective section – 'To increase RSA sales by identifying new patients in Actonel friendly surgeries. To identify, evaluate and optimise treatment in … Actonel friendly surgeries. To increase Actonel new patient share post audit in surgeries'.
- Business return section - The complainant alleged that it was evident that this was completely unacceptable.
- Description section – 'We identify Actonel friendly surgeries and nominate to …'.
- Process section – '(2) Identify Actonel first line surgery, (5) Ensure all GPs would choose Actonel, (7) Monitor progress and watch sales increase'.

TOPCAT documents:

- Flowchart for selection of TOPCAT surgeries - Ensure all GPs are first line (if no, 'Rectify issues'). Also 'Profile chemists and other practice staff for information on progress and products used'.
- TOPCAT Surgery Nomination Form - Checklist section: 'Surgery preferred bisphosphonate therapy for all licensed indications is Actonel'. Also in the Project Review section on the back of the form - 'Patients prescribed Actonel % and number and Extra sales - RSA'.
- TOPCAT Briefing Documents - Point 1.1 and the rest of the document made repeated reference to your practices. Also point 1.3 stated 'It (TOPCAT) is for use with computerised practices: (a) where Actonel is first line'. Also point 1.6 highlighted that TOPCAT was complementary to the … nurse audit programme.
- Point 2 stated 'What can it deliver to you in sales'.
- Point 3 stated 'How do I sell TOPCAT to GP practices'.

The complainant alleged that for either company to deny the nature and purpose of these representative briefing documents beggared belief. Any member of the Appeal Board that had worked in the commercial section of the UK pharmaceutical industry for longer than 6 months would clearly see these documents for what they were. More importantly, these documents were sourced from representatives working within the ABBH for both Aventis and Procter & Gamble that had participated in implementing these programmes.

The complainant alleged that it was this final point that was the most alarming of this entire case. The companies had been caught red-handed for unethical practice - the most sensible thing to have done in this circumstance would have been to have raised their metaphorical hands and accept due sanction. The foundationless nature of the grounds for appeal were an act of utter desperation. However, such reprehensible misleading of the Authority should not go unpunished. The severest of sanctions at the Board's disposal should be considered as a result of this unethical appeal as the ABBH had attempted to undermine the credibility and operational effectiveness of the Authority to self-regulate.

The complainant was stunned at the companies' suggestion that the briefing documents in question were not provided to sales staff and perhaps merely served as 'positioning documents' for head office staff. Perhaps a reminder needed to be made that the Code applied to all activities and staff of a pharmaceutical company and was not limited in scope and application to field-based employees. Furthermore, and far more importantly, this defence was a blatant lie. The complainant unequivocally assured the Authority that the documents were sourced independently from several members of the ABBH field-based sales force, for further clarity, from employees of both companies (the complainant did not bring these allegations to bear lightly, without extensive evidence gathering and so without absolute certainty that a case needed to be answered). To suggest to the contrary beggared belief. In this regard, the complainant was pleased that the Panel had noted the following:

- The Nurse Audits document (ref CP&S UK MDO) bottom text box 'For more information - Please contact your RBM (regional business manager) for further information and details of the local nurse areas'. Furthermore, the same document's 'Business Return' section stated 'Increase of your sales of £9171.70 for each practice nominated over the first year' - who on Earth do the respondents suppose the word 'your' referred to in this sentence?! Obviously, the 'yours' in question were members of

the sales force responsible for introducing the programme to 'their' surgeries. Head office staff did not report to regional business managers as anyone having worked in commercial pharma would know.

- The TOPCAT Briefing Document repeatedly used the word 'your practices' and provided a sales story … why would this be provided to anyone other than a representative? The complainant suggested that the Authority contact the named individual who would be able to advise the Appeal Board which employees would make contact regarding these programmes ie sales force or head office staff and which functions received the briefing documents.

Additional points for the Appeal Board to consider:

- To state the obvious, Sanofi-Aventis represented the product of a merger between Sanofi and Aventis. The notion that a case should not be brought against Sanofi-Aventis because it represented a separate legal entity relative to its two prior constituents' elements was utterly specious. It might be unfortunate for Sanofi-Aventis to be tarnished by these historical events, but this was hardly ancient history and so the legacy of this reprehensible behaviour lay at the doors of both Procter & Gamble and Sanofi-Aventis.

- An email asking the sales forces to complete the SOP online training dated February 2004 indicated that the entire field force was still involved and was in conflict with the suggestion in the companies' response that the project was being wound down as of the fourth quarter of 2003.

In relation to the testimonial regarding the value and probity of the programme from a GP with a specialist interest in osteoporosis, was the GP shown the materials submitted with the complaint prior to writing this testimonial to inform him of the nature of the issue with this programme? If not, respectfully, this testimonial was of no significance and should not be considered as credible or relevant by the Appeal Board.

- An email from a Procter & Gamble employee dated 7 November 2001 stated one criteria of the pilot work to be the consideration of the 'Current bisphosphonate of choice' - this email suggested a relationship between service provision and prescribing behaviour.

Furthermore, the NICE Technology Appraisal 87, Paragraphs 3.2, 3.3 and 3.4 included the following national shares of the bisphosphonate market in England for the period 2003/2004 and national case sales for this period:

Alendronate (Fosamax - MSD) £66M pa	61%
Etidronate (Didronel - P&G) £13.7M pa	23%
Risedronate (Actonel - ABBH) £16M pa.	16%

The complainant noted that the Authority had established from the ABBH that 351 practices nationally were involved during 2003/2004 serving patient populations of 2.2 million representing ~3.8% of the UK population. Furthermore, of 28,280 patients screened, 16,759 were treated with any medicine of which 15,046 were treated with Actonel. Accordingly 88% of treated patients were treated with Actonel; 88% versus a national market share during the same period of 16% was such a disparity on a programme of such scale. Or did this data serve to unequivocally support the crux of the complainant's allegations which were supported by documentation obtained from ABBH sales force members during 2006 (which remarkably seemed extraordinary difficult for the companies to source themselves in the course of this complaint on account of fires, mergers and IT updates)?

The complainant alleged that the documents he provided to the Authority in combination with the materials presented by the companies and the enormous disparity between national and ABBH programme prescribing habits illustrated that the Panel was correct to rule breaches of Clause 18.1 and 2. On these grounds the appeal should be rejected, and the matter be referred to the ABPI Board of Management for consideration of further sanctions on account of the utterly inappropriate attempts undertaken by the ABBH in the course of this appeal.

COMMENTS FROM THE COMPLAINANT ON THE FURTHER SUBMISSIONS BY THE RESPONDENTS

The complainant commented upon the documents from Procter & Gamble firstly, and where not duplicated added additional comments regarding the Sanofi-Aventis documents.

The complainant's first point was that he was a current employee of Sanofi-Aventis in the UK. The conduct of the complainant's employer in the course of this case had illustrated precisely why this case needed to be raised anonymously. Accordingly, to protect his identity and the identity of individuals that had provided documents and insight regarding the conduct of the programmes in question the complainant must remain anonymous.

The complainant alleged that the submission from Procter & Gamble that the Panel had relied upon documents that were never used to implement the nurse audit or TOPCAT programmes was categorically untrue. The documents provided to the Authority were sourced from a member of the ABBH sales team responsible for implementation of this programme (employed by Sanofi-Aventis to be precise). The complainant subsequently discussed the conduct and operational procedures of the programmes with a number of individuals employed in the ABBH sales force between 2002 and 2004 who all confirmed an unequivocal link between service provision and business metrics for Actonel within the target surgeries. Furthermore, all of the individuals, representing both member companies of the ABBH, confirmed that all members of the sales teams were absolutely clear that the programme was a very

important tool to drive Actonel sales.

The complainant stated that it was self-evident that he had obtained the materials from someone. Clearly, this was not a member of the marketing function.

The complainant stated that were his comments above not to reflect the facts of the case, the notion that documents acknowledged by both parties as having existed were acceptable as internal head office briefing documents was not consistent with the Code. Marketing teams must strictly adhere at all times to the letter and spirit of the Code and exceptions were not made for documents intended to persuade senior managers of the company to provide ongoing support to marketing led so-called service to medicine programmes.

Furthermore, the complainant alleged that the email of 7 November 2001 contradicted the claims of Procter & Gamble's employee that no link existed between service provision and prescribing behaviour:

'The pilot will run through November. In the meantime if any of you have any nominations of surgeries who you feel may be interested in participating in an osteoporosis audit please supply the following details to your RBM:
Surgery location
Patient practice size
Number of GPS
Current bisphosphonate of choice.

Please do not offer the service to our customers, simply gather information on interested parties in the event we scale up after the pilot.
Please direct all questions to myself.'

The complainant requested the Appeal Board to establish from Procter & Gamble why 'Current bisphosphonate of choice' was a required detail in relation to the pilot practices and how this did not constitute an evidential link between prescribing behaviour and provision of service as early as the pilot phase of the nurse audit programme.

In response to Procter & Gamble's submission that it believed the 88% figure referred to was not credible, the complainant noted that firstly this specific piece of data was provided by Procter & Gamble which stated from data provided from the nurse audit programme, from March 2003 to October 2004, 351 practices were audited, involving 2,203,612 patients. 28,280 patients were invited for screening by their GPs, of which 16,759 were treated with any therapy. 15,046 (53%) of screened patients were treated with risedronate (88% of all treated patients). Procter & Gamble also stated that from the TOPCAT programme, 72 practices were nominated for use of this audit tool in 2004, involving 272,322 patients. 2,956 patients were identified as being at risk of osteoporosis. Approximately 60 patients were initiated on Actonel in this timeframe.

The complainant had stated that his research had established that 424 practice based audits had taken place resulting in 17,532 patients receiving bisphosphonates, the vast majority of which being Actonel. This data was sourced from an individual employed within the ABBH sales team during 2002-2004. Combination of the data from Procter & Gamble for both the nurse audit and TOPCAT equated to 423 practice based audits and 15,106 patients on Actonel. Application of 88% market share of bisphosphonate treated patients to the number of bisphosphonate treated patients identified by the complainant's original research (ie 17,532) would equate to 15,428. Whilst circumstantial evidence, given that the complainant did not acquire copies of the materials documenting the number of audits and patients treated, the complainant hoped that the remarkably consistency of the numbers reported in the original complaint with that from Procter & Gamble provided the Appeal Board with further reassurance of the lengths to which the complainant had gone to, to ensure that a complaint needed to be answered before bringing this to the attention of the Authority.

The complainant referred to cases that were practically identical in nature to Cases AUTH/1902/10/06 and AUTH/1903/10/06 (Cases AUTH/1807/3/06, AUTH/1810/3/06 and AUTH/1814/3/06). In both cases breaches of Clause 2 in addition to Clause 18.1 were ruled. Accordingly, if the Authority was to issue consistent sanctions and the Clause 18.1 breach in the current case was upheld, a breach of Clause 2 was entirely appropriate.

The complainant noted the statement from the Procter & Gamble employee and made the following comments: 'I should say that there was, at no point in any of these materials, a suggestion that participation in the programme was linked to prescription of any medicine and no reference to risedronate at all'. The complainant referred the Appeal Board to another section where the employee failed to provide an explanation of the reference to current bisphosphonate of choice when selecting pilot practices in the email of 7 November 2001.

'Representatives were instructed to conduct a standard sales call to discuss use of risedronate for the treatment of osteoporosis. If the relevant doctor had previously prescribed risedronate to any of his patients or displayed some interest in prescribing risedronate, the representative would request a second non-promotional appointment to discuss the Nurse Audit Programme. (If a particular doctor indicated that, where a bisphosphonate was indicated, he would only prescribe a product manufactured by one of our competitors (eg Fosamax) and would not consider risedronate, then representatives would not routinely book a second appointment to discuss the Nurse Audit Programme. Nevertheless, this did not mean that practices who did not prescribe risedronate were excluded and some such practices did, in fact, participate in the Programme)'. The complainant alleged that this was a mis-representation of the protocol for briefing representatives. Regional sales managers would, during the primarily oral briefings discuss the TOPCAT Briefing Document, TOPCAT flowchart and the Nurse Audits document (ref CP&S UK MDO).

'If the relevant doctor had previously prescribed risedronate to any of his patients or displayed some interest in prescribing risedronate, the representative would request a second non-promotional call to discuss the Nurse Audit programme. (If a particular doctor indicated that, where a bisphosphonate was indicated, he would only prescribe a product manufactured by one of our competitors (eg Fosamax) and would not consider risedronate, then representatives would not routinely book a second appointment to discuss the Nurse Audit Programme)'. The complainant alleged that this statement confirmed that selection of the offer of an audit programme relied upon the doctor's prescribing habits. Whilst the doctor in the circumstance described above had not been requested to prescribe a particular medicine in return for provision of the service, the representative had linked service provision to business metrics by pre-selecting those surgeries to be offered the service as described in the statement. Furthermore, what guidance was offered to the representative when a GP that would not prescribe Actonel heard about the service from a colleague that did (and therefore had received the service) and asked the representative to place an audit in his surgery? The answer to this obtained from the complainant's contacts within the sales organisation was that the non-Actonel prescribing GP would be placed on a 'waiting list' and the representative recommended to steer clear of that particular surgery for a healthy interval.

'During the second call, the representative would discuss the Nurse Audit Programme and if the practice appeared one where the programme would be of use (eg because of the ages of patients served by that practice and the fact that a similar audit had not been conducted in the previous 2 years) and the GPs wished to participate, the representative would nominate the practice for approval. The level of risedronate prescribing was not a factor which determined whether a practice would be nominated. (This is confirmed by the list of factors included in the Sales Force Call Agenda under 'Assessment of Suitability for Osteoporosis Review') …. Details of approved practices were passed to the … nurses who would then initiate contact with the practices. From that stage, ABBH and the staff of its member companies had no further involvement in the Programme'. The complainant alleged that it was categorically untrue as described above.

'Such an approach (i.e. selection of first line surgeries only) would have been wholly unrealistic in the context of risedronate's limited market share'. The complainant stated that representatives were required to consider expressed prescribing behaviour for new patient episodes. At the time, <10% of osteoporotic patients were treated with any RCP endorsed therapies. Accordingly, the existing market was minimal and therefore the total market share was not the representatives' interest … the 'dynamic' or intended future prescribing behaviour would determine whether GPs would be offered the service. This of course might be known to the representative from their routine promotional calls on the GPs to whom they would introduce the service. Accordingly, how any call from a representative could be completely divorced from promotional agendas presented a larger question of the wisdom of Clause 18.1 in its current form.

'… from November 2003, … I had overall responsibility for marketing. I have therefore been asked to comment in relation to the … Nurse Audit Document (Ref CP&S UK MDO) which was seemingly generated by Procter & Gamble in May 2004. A copy of this document was found in a file containing draft documents and final material used for a sales conference in May 2004, although I do not believe the document was used at the conference. In May 2004, the person with responsibility for the Nurse Audit Programme at Procter & Gamble was an individual, who is no longer with the company. He was, at that time, subject to a performance review and his work was closely supervised. Any documentation generated by him that was intended to be released to the sales force would have been first reviewed by me as his line manager. However, prior to this investigation, I had not seen or been asked to review the … Nurse Audit Document. I am therefore confident that it was not used to brief representatives in relation to the … Programme'. This contention was flawed. The complainant repeated that the documents provided to the Authority were sourced from an ABBH sales team member and familiar to several other sales team members at both Sanofi-Aventis and Procter & Gamble.

The complainant alleged that a statement from a second Procter & Gamble employee, 'The second non-promotional call was not routinely requested if a particular doctor indicated that, where a bisphosphonate was indicated, he would only ever prescribe a product manufactured by one of our competitors (e.g. Fosamax) and would never consider risedronate' as above, confirmed a selective link between provision of the service in question and prescribing behaviour. The purpose of the second non-promotional call was to separate sales activity from service provision … accordingly, the representative should not determine whether the second non-promotional call took place at all on the basis of the GP's prescribing behaviour.

With regard to Sanofi-Aventis' submission the complainant stated that the first issue with a doctor's submission was whether he had been fully informed of the documents provided to the Authority that had formed the basis of this complaint. If not, he had not been transparently informed of the issue with the ABBH programmes. There was no question that the service was beneficial to GPs and their patients, particularly so in areas lacking NHS diagnostic and assessment infra-structure. That was an entirely separate point to the issue of Code compliance of the programme from the perspective of an inappropriate linkage of service to prescribing behaviour.

Furthermore, respectfully, the relevance of this testimonial should be measured in light of the doctor's acknowledgment that: 'Several years had elapsed since the Programme was concluded and I now had little recollection of its details'.

The complainant was very disappointed that he felt unable to attend the appeal hearing for fear of diminishing his future employability in the pharmaceutical industry. Like many of his colleagues, the complainant considered that the UK pharmaceutical industry was sitting on a precipice in respect of its likelihood of maintaining the privilege to self-regulate its business practices. Decisive action must be taken against those whom would endanger self-regulation because the consequences of introducing a body such as the FSA in their sphere of business would be catastrophic for the collective reputations and make day-to-day business activities far more cumbersome than was currently the case. Therein laid the complainant's motivation to bring this case to bear. The last four months or so had been quite the worst of his professional life, however, the truth must be made apparent. The complainant sincerely hoped that the Appeal Board considered the evidence placed in front of it, rejected the appeal and ruled breaches of Clauses 18.1 and 2.

The complainant alleged that the conduct of the ABBH in the course of this appeal had almost rendered the actual case in hand a secondary issue. There could be no excuse for denial of the truth and mis-representation of the facts to the Authority. Sadly, the complainant hoped that the conduct of the ABBH in the course of these cases would result in the Appeal Board referring the case to the ABPI Board of Management. The ABPI could ill-afford in these difficult times to have member companies that demonstrated contempt for the letter and spirit of the Code; suspension if not expulsion might serve as an appropriate sanction that would focus minds across the industry on how the industry should conduct itself.

APPEAL BOARD RULING

The Appeal Board noted that the nurse audit, which ran from 2002 until 2004 was sponsored by the ABBH which comprised Procter & Gamble and Aventis. Aventis had since merged with Sanofi to become Sanofi-Aventis.

The Appeal Board noted that Clauses 2 and 18.1 of the 2003 Code were the same as Clauses 2 and 18.1 of the 2001 Code and thus considered the matter under the 2003 Code. The supplementary information to Clause 18.1 of the 2001 Code was the same as the supplementary information to Clause 18.1 of the 2003 Code ie that medical and educational goods and services which enhanced patient care or benefited the NHS could be provided within certain conditions.

The Appeal Board noted that the material for health professionals referred to the ABBH and bore a declaration of sponsorship which referred to Aventis and Procter & Gamble. Some material for internal use such as the Programme: Update and Changes to Osteoporosis Review document (ref A2121) provided by Procter & Gamble bore the names of each company but not the ABBH. A document Programme: RBM Responsibilities (June 2003) also bore the reference number A2121 and mentioned the Alliance.

The Appeal Board noted that osteoporosis was a serious disease and that a service which would increase diagnosis and treatment would be of benefit to patients. Nonetheless any such service had to comply with the Code.

The Appeal Board was concerned about the limited documentation provided by the companies. It noted the companies' explanations in this regard. In relation to the material provided by the complainant the Appeal Board noted that whilst it was possible to contact the complainant his identity was unknown and thus it was extremely cautious when deciding what weight, if any to attach to his evidence.

The Appeal Board noted the detailed comments provided by all the parties. It also noted with concern the changes in submission by Procter & Gamble with regard to its initial acceptance of a breach of Clause 18.1 and its subsequent submission that it only accepted a breach of Clause 14 in relation to its failure to certify representatives' briefing material. It also noted that Procter & Gamble had decided that its statement that 88% of treated patients were initiated on Actonel was not true; the figure of 88% had been incorrectly calculated.

The Appeal Board noted that the parties' submissions differed. Nonetheless there were some similarities between them. The complainant had provided documents which he stated were intended to be used by representatives; Sanofi-Aventis and Procter & Gamble disagreed and stated that the documents had not been used in the field. The Appeal Board examined the sales data submitted by the companies but did not consider that such data could ever be used to demonstrate that sales staff had been appropriately briefed. The Appeal Board ultimately concentrated on two documents regarding the nurse audit which both companies agreed had been used by sales personnel; a document headed 'Actonel GP Call Agenda and Follow Up November 02 to January 03' and the Sales Force Call Agenda (June 2003) (ref A2121).

'The Actonel GP Call Agenda and Follow Up' appeared to set out the sequence of events from a sales call to an audit call. The first instruction was 'Call objective 1: Gain agreement to Rx [prescribe] Actonel as 1st choice therapy for patients with low BMD [bone mineral density], [corticosteroid induced osteoporosis], patients with previous fragility fracture'. If the call objective was not achieved then representatives were given a second call objective of 'If dosing were not an issue Gain agreement to proactively Rx Actonel 1st line for [the same group of patients]'. If the answer was still no then representatives were to do the second product detail. Conversely if call objective 1 or 2 was achieved the next step was referred to as Step 1 of the Audit call which was to 'Book another appointment with the GP with a profile objective: To gain a full understanding of GP's level of interest and commitment to conducting an osteoporosis review in the practice … WITHOUT ACTUALLY OFFERING THE [nurse audit] SERVICE'. Having done that the representative then had to book an appointment with the most influential GPs in the practice to ensure that they supported an osteoporosis

review. The Appeal Board considered that the document was in effect briefing material which instructed representatives how to offer the service. It appeared that representatives would not offer the service until they were sure that the doctors in the practice supported an osteoporosis review and would, as part of that review process, prescribe Actonel as either first choice or first line therapy to suitable patients. The Sales Force Call Agenda (June 2003) similarly showed that a doctor's agreement to prescribe Actonel as first choice therapy was the first hurdle to being offered the service. This document also included an assessment of suitability for osteoporosis review which included a cut off of a total patient population above 3,000 for the audit service to be offered.

The Appeal Board considered that companies had to be clear and unambiguous when instructing representatives about their role in such matters. The Appeal Board considered that the link between the promotion of Actonel and the provision of the service including the selection of practices as described in the material was unacceptable. The Appeal Board did not accept the companies' submission that the two documents clearly separated the sales and non promotional calls. The Appeal Board considered that neither the content or layout of either document were satisfactory in this regard. The companies acknowledged that the layout of the documents was 'unfortunate'.

As an indication as to how the service was offered in practice, the Appeal Board noted a statement from one of Procter & Gamble's employees. The employee stated 'If a particular doctor indicated that, where a bisphosphonate was indicated, he would only prescribe a product manufactured by one of our competitors (eg Fosamax) and would not consider risedronate [Actonel], then representatives would not routinely book a second appointment to discuss the Nurse Audit Programme. Nevertheless, this does not mean that practices who did not prescribe risedronate were excluded and some such practices did, in fact, participate in the Programme'.

Notwithstanding the statement that some surgeries which did not prescribe Actonel were offered the service, the Appeal Board considered that the link in the representatives' material between the promised prescription of Actonel by the doctor and the subsequent offer of the service by the representative was unacceptable. It considered that the criteria for the selection of practices and the failure to adequately separate the promotional and non promotional role of the representatives was such that the arrangements failed to comply with the requirements of Clause 18.1.

The Appeal Board upheld the Panel's ruling of a breach of the Code. The appeal on this point was unsuccessful. The Appeal Board considered that the concerns about the material which gave rise to a breach of Clause 18.1 were so serious that they brought discredit upon and reduced confidence in the pharmaceutical industry. The Appeal Board upheld the Panel's ruling of a breach of Clause 2. The appeal on this point was unsuccessful.

The Appeal Board noted its comments above about the weight to be attached to the evidence. The Appeal Board considered that there was insufficient evidence to establish, on the balance of probabilities, whether the arrangements for the TOPCAT service complied with the Code. The Panel's ruling in this regard no longer stood. Accordingly, there was no breach of the Code in relation to arrangements for the TOPCAT service.

The Appeal Board noted the Panel's report in accordance with Paragraph 8.2 of the Constitution and Procedure. The Appeal Board noted its comments above and its rulings of breaches of the Code in relation to the nurse audit programme. The Appeal Board was concerned about the paucity of documentation provided by both companies in all circumstances. The Appeal Board decided, in accordance with Paragraph 11.3 of the Constitution and Procedure, to require an audit of both companies' procedures in relation to the Code to include an examination of policies and procedures relating to the ABBH. On receipt of the audit reports the Appeal Board would decide if any further action was required.

Upon receipt of the audit report of Sanofi-Aventis, the Appeal Board decided that on the basis that the recommendations were implemented no further action was required.

Upon receipt of the audit report of Procter & Gamble, the Appeal Board considered that there was much work still to be completed to implement the recommendations and it was concerned about the inadequacy of the certification arrangements. The Appeal Board decided that Procter & Gamble should be re-audited in January 2008.

Complaint received	**19 October 2006**
Undertakings received	
Case AUTH/1902/10/06	**23 May 2007**
Case AUTH/1903/10/06	**24 May 2007**
Report to the Appeal Board	**19 April 2007**