CASE AUTH/2101/2/08

ANONYMOUS EMPLOYEE v GLAXOSMITHKLINE

Diabetes care package

An anonymous employee of GlaxoSmithKline complained about the arrangements for the Diabetes Healthcare Partnership (HCP) which existed between GlaxoSmithKline and a primary healthcare service company. The primary healthcare service company delivered a range of services under the contractual opportunities offered by practice based commissioning (PBC).

The complainant stated that (s)he was a Diabetes First Associate (DFA), a non-promotional representative and former nurse, with GlaxoSmithKline. The complainant referred to a voicemail from a senior member of staff in integrated healthcare to UK Pharma.

> **'... some of the feedback from our customers, particularly practice based commissioning groups, is they want a transparent business-to-business relationship with GlaxoSmithKline, so that they are clear when they work with us of the benefit to GlaxoSmithKline, to the NHS, and to patients. So with this in mind we have been working on a new proposition, "The GSK Healthcare partnership." And we have now reached an important milestone where the first partnership contract has been signed with [a primary healthcare service company], a Practice Based Commissioning Group based in [a local area]. This collaboration… involves the delivery of a bespoke diabetes care package, "The Diabetes Intermediate Service". This innovative service created with the assistance of GSK aims to reduce the number of secondary care referrals by the deployment of a consultant lead [sic] team. GSK's expertise has been central to the development of this service, in addition GSK has contributed to the cost of running of the service, while [the primary healthcare service company] has agreed to select Avandamet [rosiglitazone and metformin] as first medicine in it's [sic] class on it's [sic] diabetes protocol for appropriate patients. This is a contractual arrangement between two commercial organisations. Together we have agreed specific roles, responsibilities, and deliverables. All aspects of the collaboration and on-going customer interaction fit with appropriate ethical guidelines. So this … is a major achievement and a significant step forward in establishing a more mature and potentially a more effective business relationship between GSK and the NHS. Where tangible benefits to all parties are clearly defined from the outset and are consistent with our "Sharing the Vision" philosophy ... '.**

The complainant had asked his/her manager about the voicemail and been told everything was completely signed-off, but it did not seem to fit within the spirit of the Code. The voicemail was sent out by customer environment marketing in September 2007, which managed the integrated healthcare managers and did unusual projects with the NHS.

Was it within the Code to have this business-to-business relationship as described? It just seemed like a clever way to pay for a service and generate more prescriptions as a result. The complainant had been told that everything (s)he did was a service to medicine where there was no influence on what a customer prescribed. In this partnership, it seemed that the company had called it a business relationship and only provided the service with the primary healthcare service company's agreement to put Avandamet in its protocol over competitors. The complainant's manager said this was okay because it was only a protocol and the GP could prescribe whatever they wanted. The complainant queried whether (s)he would want to read about this in the newspaper.

The complainant queried whether these healthcare partnerships were in keeping with the relevant and specific sections of the Code, and more importantly in keeping with its spirit.

The Panel noted that joint working between the industry and the NHS was not prohibited by the Code providing all the arrangements complied with it. In general arrangements that increased the potential pool of treated patients were likely to be acceptable. Arrangements that increased the prescribing of one specific product were likely to be unacceptable. The Panel accepted that a service that improved clinical outcomes, standardized continuity of care and reduced the number of secondary care referrals, all aims of the service at issue, would enhance patient care and benefit the NHS.

The Panel noted that the complaint had been prompted by a voicemail message which referred to the company's business relationship with the primary healthcare service company whereby GlaxoSmithKline had agreed to help the primary healthcare service company achieve its objective of reducing the number of diabetic patients referred to secondary care by deploying a specialist team, led by a consultant diabetologist, in the primary care setting. The voicemail stated that '… GlaxoSmithKline has contributed to the cost of running the service, while [the primary healthcare service company] has agreed to select Avandamet as first medicine in its class on its diabetes protocol for appropriate patients. This is a contractual

agreement between two commercial organisations'. The complainant was concerned that GlaxoSmithKline's sponsorship of the service was dependent upon the inclusion of Avandamet on the protocol.

The Panel noted guidance issued by the DoH in January 2008 on joint working between the NHS and the pharmaceutical industry defined joint working as:

> **'Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme…'.**

The Panel noted that GlaxoSmithKline had referred to this definition albeit one that was published some four months after the contract with the primary healthcare service company had been signed. The Panel noted that GlaxoSmithKline had helped the primary healthcare service company to develop its first diabetes pilot project by providing financial support, facilitation and training. In the Panel's view, however, the relationship between the primary healthcare service company and GlaxoSmithKline in the service now at issue did not appear to be one whereby the two organisations had pooled skills, experience and/or resources; it appeared that GlaxoSmithKline had acted simply to co-fund, or sponsor, the primary healthcare service company's diabetes service. In that regard the Panel noted GlaxoSmithKline's submission that its contract with the primary healthcare service company supported the running of the Diabetes Intermediate Service through funding to a maximum of £29,250 and that the company had no other involvement in the selection of the medicine for the management protocol and was not involved in any way in the management or provision of the service.

The Panel noted that GlaxoSmithKline had submitted that its relationship with the primary healthcare service company was at a business-to-business level and not with individual prescribers. GlaxoSmithKline described this as an explicit and transparent separation. In the Panel's view, however, GlaxoSmithKline was in effect working with a third party which it knew would influence the prescribing of individual doctors.

The contract between the primary healthcare service company and GlaxoSmithKline was dated September 2007. Paragraph 3.1 stated 'This project is sponsored by GSK. As a consequence of [the primary healthcare service company's] decision to place GSK's product on [the protocol] in accordance with paragraph 2.6 above, GSK has agreed to provide funding for this service: provisions of such funding is not conditional on the prescription of that product'. Other paragraphs defining GlaxoSmithKline's involvement related to the payment of the agreed funding, the use of any data provided to GlaxoSmithKline and that GlaxoSmithKline would comply with best practice to include codes of practice, relevant laws and guidelines on confidentiality and data protection.

Paragraph 2.6 of the contract stated 'Subject to paragraphs 2.7 and 2.8 below, [the primary healthcare service company] has agreed to select AVANDAMET ("the product") as a first choice medicine in its therapy class for the appropriate patient group on the Protocol ("First Choice Medicine"). Such selection by [the primary healthcare service company] shall include all considerations as per paragraph 2.2 above'. Paragraph 2.2 stated that the choice and use of medicines within a protocol was based upon the medicine's marketing authorization, an up-to-date review of the available evidence and its cost effectiveness. The protocol was for use by all the primary healthcare service company's practices. It was, presumably, paragraph 2.6 which had led to the statement in the voicemail that '[The primary healthcare service company] has agreed to select Avandamet as first medicine in its class on its diabetes protocol …'.

Paragraphs 2.7 and 2.8 of the contract made it clear that GlaxoSmithKline's medicines, including Avandamet, would only be used where appropriate and in accordance with local guidelines. Further, GPs in the group would retain clinical freedom for any individual patients for whom, in the GP's opinion, use of Avandamet was inappropriate. Paragraph 2.16 stated that GlaxoSmithKline would be provided with anonymised data relating to prescribing and outpatient outcomes.

The Panel noted that in response to a request for further information GlaxoSmithKline provided a copy of the diabetes protocol dated March 2007, due for review by March 2008, which it submitted was the first time the company had seen it. Under a heading of 'Glycaemic Control' for type 2 diabetics it was stated that step 2 treatment, for all patients with a body mass index of 25 or more, should be:

'Add Glitazone to metformin
- **1st line: pioglitazone**
- **2nd line: rosiglitazone**

Increase dose up gradually as required to maximum.

Glitazones are slow acting drug so results will not be noticeable immediately; reduction of blood glucose will happen over 4 - 6 weeks.

If there are compliance problems the combination tablets of Glitazone/metformin may be used…'

It thus appeared that the protocol and paragraphs

2.6 and 3.1 of the contract were inconsistent with one another. In the protocol rosiglitazone was stated to be the second line glitazone and in any event the combination tablets ie Avandamet, were only to be used if there were compliance problems. Given the protocol as it existed (effective from March 2007 and due for review by March 2008) the Panel queried why the contract was signed in September 2007 containing paragraph 2.6 specifically referring to Avandamet as a first choice medicine in its therapy class. The protocol referred to products by generic name only.

The Panel considered that, notwithstanding the protocol, paragraph 3.1 of the contract signed by GlaxoSmithKline in effect stated that the company's funding of the diabetes service was dependent upon the inclusion of Avandamet, as a named medicine, on the protocol. This was also the impression given in the voicemail. The Panel noted that the provision of medical and educational goods and services must not be linked to any medicine. In that regard the Panel considered that the diabetes service as described in the voicemail and in the contract was inappropriate. A breach of the Code was ruled. High standards had not been maintained. A breach of the Code was ruled. These rulings were appealed.

With regard to whether or not the arrangements amounted to an inducement to members of the health professions or administrative staff to prescribe, supply, administer, recommend, buy or sell Avandamet, the Panel noted that there was no gift, benefit in kind or pecuniary advantage to the actual prescribers. However the prescribers, as employees of the primary healthcare service company, would be obliged to follow the protocol. As far as GlaxoSmithKline was concerned the effect of the arrangements was that a payment had been made to a private company such that Avandamet was recommended. The Panel was concerned about the arrangements but after much consideration decided that, on balance, the circumstances of providing an inducement to the primary healthcare service company did not amount to a breach of the Code and ruled accordingly.

The Panel was concerned that the diabetes service was seen by some in GlaxoSmithKline as being linked to the use of Avandamet as first medicine in its class. The Panel noted that, given the content of the protocol and unbeknown to GlaxoSmithKline, as operated, the diabetes service was not linked to the use of Avandamet. The Panel thus considered that on balance, taking all the circumstances into account, GlaxoSmithKline had not brought discredit upon, or reduced confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

Upon appeal by GlaxoSmithKline the Appeal Board noted that the question to be answered was 'Did GlaxoSmithKline support the Diabetes HCP in return for Avandamet being named on the group's protocol?' The Appeal Board noted inconsistencies between the voicemail message, the written contract, and the protocol. The Appeal Board considered that it had to make its ruling on the service as described by GlaxoSmithKline in the voicemail and contract, as opposed to the protocol.

The Appeal Board noted that the voicemail message stated that '… GlaxoSmithKline has contributed to the cost of running of the service, while [the primary healthcare service company] has agreed to select Avandamet as first medicine in its class on its diabetes protocol for appropriate patients'. A direct link between the company's support and the potential use of Avandamet was thus implied. Paragraph 3.1 of the contract between the primary healthcare service company and GlaxoSmithKline stated 'This Project is sponsored by GlaxoSmithKline. As a consequence of the Group's decision to place GlaxoSmithKline's product on the Group's Protocol in accordance with paragraph 2.6 above, GlaxoSmithKline has agreed to provide funding for this service: provision of such funding is not conditional on the prescription of that product'. In the Appeal Board's view it was immaterial that the protocol did not refer to Avandamet as a named medicine; that it would do so was the basis upon which the contract was signed.

At the appeal hearing GlaxoSmithKline acknowledged that the wording used in paragraph 3.1 of the contract was not the best it could be.

The Appeal Board noted GlaxoSmithKline's submission that the protocol had existed before its involvement with the Diabetes HCP and that the company had not influenced it in any way; it had not changed as a result of the contract between the primary healthcare service company and GlaxoSmithKline. This was not the impression given by the voicemail and the contract.

The Appeal Board noted the protocol stated that when a glitazone was to be added to metformin, rosiglitazone was second line. Combination tablets of glitazone and metformin were only to be used if there were compliance problems. It also noted GlaxoSmithKline's submission that the positioning described was consistent with National Institute for Health and Clinical Excellence (NICE) guidance.

The Appeal Board further noted GlaxoSmithKline's submission that the naming of Avandamet in the contract was for the purposes of transparency. The Appeal Board considered that in this regard it was not inappropriate *per se* to refer to products but the manner in which they were referred to and the context was important. Encouraging appropriate use of a product in line with national and local guidelines was different to a contractual arrangement that a protocol be changed. The Appeal Board considered that in the voicemail and in the contract there was a very definite, unequivocal link made between the provision of funding and the inclusion of Avandamet, for use as appropriate, on the protocol.

The Appeal Board noted that GlaxoSmithKline's sponsorship of the Diabetes HCP (£29,250) had part-funded a diabetes nurse. The Appeal Board further noted that the Diabetes HCP was the mechanism by which the primary healthcare service company delivered its diabetes service. The relationship between the primary healthcare service company and GlaxoSmithKline was an evolving relationship. GlaxoSmithKline provided the primary healthcare service company with, *inter alia*, education, training and business planning. The two organisations worked together on, *inter alia*, project management, data analysis and communications.

The Appeal Board considered that the Diabetes HCP had merit. However the way it had been described in the voicemail and the manner in which Avandamet had been referred to in the contract was evidence that the provision of funding had been linked to the product. The Appeal Board upheld the Panel's ruling of a breach of the Code. The appeal on this point was thus unsuccessful.

Although noting its ruling above the Appeal Board nonetheless did not consider that taking all the circumstances into account that GlaxoSmithKline had failed to maintain high standards. No breach of the Code was ruled. The appeal on this point was successful.

An anonymous employee of GlaxoSmithKline UK Ltd complained about the arrangements for the Diabetes Healthcare Partnership (HCP) which existed between GlaxoSmithKline and the primary healthcare service company. The primary healthcare service company delivered a range of services to general practice under the contractual opportunities offered by practice based commissioning (PBC).

COMPLAINT

The complainant stated that (s)he was a Diabetes First Associate (DFA), a non-promotional representative and former nurse, with GlaxoSmithKline. The complainant wanted anonymity as the company was currently being restructured and (s)he did not want this to potentially impact the chance of future employment.

The complainant referred to the following voicemail:

> 'Hi, this is … with a message to UK Pharma. As you know I have been looking at ways to improve how effectively we listen to our external customers, particularly in light of our "Temperature Check" scores on this particular area. In some of the feedback from our customers, particularly practice based commissioning groups, is they want a transparent business-to-business relationship with GlaxoSmithKline, so that they are clear when they work with us of the benefit to GlaxoSmithKline, to the NHS, and to patients. So with this in mind we have been working on a new proposition, "The GSK Healthcare partnership." And we have now reached an important milestone where the first partnership contract has been signed with [a primary healthcare service company], a Practice Based Commissioning Group based in [a local area]. This collaboration with GSK and [the primary healthcare service company] involves the delivery of a bespoke diabetes care package, "The Diabetes Intermediate Service". This innovative service created with the assistance of GSK aims to reduce the number of secondary care referrals by the deployment of a consultant lead [sic] team. GSK's expertise has been central to the development of this service, in addition GSK has contributed to the cost of running of the service, while [the primary healthcare service company] has agreed to select Avandamet as first medicine in it's [sic] class on it's [sic] diabetes protocol for appropriate patients. This is a contractual arrangement between two commercial organisations. Together we have agreed specific roles, responsibilities, and deliverables. All aspects of the collaboration and on-going customer interaction fit with appropriate ethical guidelines. So this implementation of this first "GSK Healthcare Partnership" is a major achievement and a significant step forward in establishing a more mature and potentially a more effective business relationship between GSK and the NHS. Where tangible benefits to all parties are clearly defined from the outset and are consistent with our "Sharing the Vision" philosophy. Many of our customers are excited and motivated to explore similar partnerships and to this end at least 40 projects across a range of therapy areas are under consideration. So at this point I'd like to take the opportunity to congratulate our colleagues who have worked tenaciously to get this first partnership up and running. In particular, [four named persons] and [the strategic partnerships manager] from Customer Environment Market Success with its implementation. I'll be in touch again to communicate outputs and further developments in due course. Bye for now.'

The complainant had asked his/her manager about the voicemail and been told everything was completely signed-off, but it did not seem to fit within the spirit of the Code. The voicemail was sent out by a vice president of customer environment marketing in September 2007, who managed the integrated healthcare managers and did unusual projects with the NHS.

Was it within the Code to have this business-to-business relationship as described? It just seemed like a clever way to pay for a service and generate more prescriptions as a result. The complainant had been told that everything (s)he did was a service to medicine where there was no influence on what a customer prescribed. In this partnership, it seemed

that the company had called it a business relationship and only provided the service with the primary healthcare service company's agreement to put Avandamet in its protocol over competitors. The complainant's manager said this was okay because it was only a protocol and the GP could prescribe whatever they wanted. It did not seem to pass the newspaper test – the complainant queried whether (s)he would want to read about this in the paper.

The complainant encouraged the Authority to request information on these healthcare partnerships and investigate whether they were in keeping with the relevant and specific sections of the Code, but more importantly in keeping with spirit of the Code.

When writing to GlaxoSmithKline, the Authority asked it to respond in relation to Clauses 2, 9.1 18.1 and 18.4 of the Code.

RESPONSE

GlaxoSmithKline noted that the Ministerial Industry Strategy Group (MISG), a joint industry and Department of Health (DoH) high-level group, brought together government and pharmaceutical industry representatives as part of the follow-up to the implementation of the Pharmaceutical Industry Competitiveness Task Force (PICTF) recommendations. MISG was set up following a conclusion in the March 2001 PICTF Report that a new high-level group was required to take the government/industry relationship forward at a strategic level. MISG was co-chaired by a minister of health and a senior industry executive and included governmental, industry and ABPI representation, including the Director General of the ABPI. The MISG had developed the following agreed vision of partnership working:

'The industry can bring more than just medicines to the NHS and the patients it serves in the form of skills and expertise to support top quality and productive services. For this to happen, however, a more "mature" relationship has to be developed between the industry and the NHS founded on mutual respect and trust and demonstrated through successful working on areas of mutual interest and benefit.'

Further guidance had subsequently been published (18 January 2008) by the DoH supporting joint working between the NHS and the pharmaceutical industry.

'Joint working between the pharmaceutical industry and the NHS must be for the benefit of patients or the NHS and preserve patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner. All such activities, if properly managed, should be of mutual benefit, with the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.

For the purpose of this guidance, joint working is defined as follows:

Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.'

GlaxoSmithKline explained that the primary healthcare service company was a limited company which delivered a wide range of services to practices under the contractual opportunities offered by PBC. GlaxoSmithKline referred to a description of the primary healthcare service company as it appeared on that company's website.

PBC groups, provider arms of PBC groups, such as the primary healthcare service company, primary care trusts (PCTs), foundation trusts and private providers operated as businesses. They were often legal entities with formalised corporate structures in place. These groups had financial responsibility for the management of patient care in a locality. Within this, their remit was to purchase and deliver high quality care, including services and medicines. Their roles and responsibilities (as with many health providers both within and outside the NHS) included the use of protocols for patient management and for the rational use of medicines. These were routinely employed to deliver a consistent standard of care to consider the needs of the population. These needs were however different to those of the individual prescribers and health professionals who specifically considered the needs of individual patients within the protocol and formulary framework.

The relationship between GlaxoSmithKline and the primary healthcare service company was at a business-to-business level with those directors who managed the company. In this relationship the roles and responsibilities were clearly defined according to an agreed contract. GlaxoSmithKline's relationship was not with individual prescribers or practices, therefore a clear separation between the business related activities of the organisation and the prescribing activities of individual health professionals was maintained. Given this explicit and transparent separation, GlaxoSmithKline believed that this relationship was compatible with the stated aims of the MISG and the DoH guidance as referred to above. Additionally GlaxoSmithKline rejected any allegation of a breach of the Code given the contractual and ethical safeguards as detailed below.

GlaxoSmithKline explained that the Diabetes Intermediate Service run by the primary healthcare service company was commissioned by a PCT during 2006. In 2007, the primary healthcare service company reviewed and improved its existing consultant-based diabetes service using dedicated staff (the diabetic intermediate team). The aim of the service was to optimally manage all aspects of diabetes in primary care, only referring patients into secondary care when absolutely necessary. The prevalence of type 2 diabetes within the area was 4%, giving a population of approximately 1,320 diabetics. It was estimated that 60-70 patients would be seen each week by the diabetic intermediate team to improve patient control and management within the the primary healthcare service company primary care environment. The projected annual cost of the service was estimated to be £117,000.

As part of the project, the primary healthcare service company reviewed and updated the diabetic database. Patients were identified and read coded appropriately. The primary healthcare service company developed a care pathway, supported by management protocols. All staff involved received training in the use and implementation of this management plan. Routine diabetic care was carried out at practice level by practice nurses which was planned to continue but, in addition, a regular diabetes educational programme was established. Practice nurses were able to access mentoring by the more experienced specialist nurses formally and informally, attending clinics as required. GlaxoSmithKline did not have any involvement in the educational programme or training.

When a referral to the specialist intermediate team was necessary, this was carried out by populating a template on the primary healthcare service company's clinical system, which was then emailed to a dedicated inbox. The Diabetes Intermediate Service lead nurse triaged these referrals and allocated the patient to the most appropriate clinician in the intermediate team. Each referral type had a dedicated read code which would help with auditing. The service was provided over three days per week.

The diabetic team for referral consisted of:

- Consultant diabetologist,
- Diabetic Specialist Nurse (DSN) specialising in poor control, insulin starts and titration,
- DSN specialising in oral management optimisation,
- GP with special interest
- Senior practice nurse, health care assistant and
- Project coordinator.

The consultant would mainly manage patients with complications or whose diabetes was extremely difficult to control. The consultant would also support the whole team as required.

GlaxoSmithKline noted that the wording of the contract underscored the principles by which the company worked with these groups. The requirements of this contract specifically excluded practices or other healthcare providers who did not have a formal protocol process or PBC type capability. The contract required a distinct separation of the contract partners and prescribers, thus ensuring clinical prescribing freedom when necessary. These principles would not allow GlaxoSmithKline to enter into such a relationship where these criteria could not be fulfilled. As such only a small selection of PBC type providers would be suitable for such a relationship. By limiting the nature of the groups available for such a relationship and ensuring these safeguards were in place, GlaxoSmithKline was able to work specifically in this way within the parameters of the MISG and DoH guidance.

The Diabetes Healthcare Partnership (HCP) aimed to bring clear and transparent benefits to patients, the NHS and GlaxoSmithKline by combining industry and NHS resources and expertise in the management of diabetes. The partnership was aligned with and responded to the government's agenda to treat more patients in the primary care environment and to achieve a sustainable improvement to the total healthcare economy.

Through the Diabetes HCP GlaxoSmithKline and the primary healthcare service company had formed a business-to-business relationship bound by a legal contract. The relationship enabled the primary healthcare service company to better manage its Diabetes Intermediate Service and thus the care of its diabetic patients according to its pre-existing protocol. The relationship was held between GlaxoSmithKline and two authorised representatives of the primary healthcare service company, the Managing Director and the Business Manager. GlaxoSmithKline firmly rejected any suggestion that this relationship was inappropriate or in breach of Clause 18.1.

Clause 18.1 referred to gifts, benefits in kind or pecuniary advantage given in relation to inducements to prescribe, supply, administer, recommend, buy or sell any medicine. As was stated above and included in the contract, the primary healthcare service company had selected Avandamet as part of its protocol for diabetes management. This had occurred in advance of the contract with GlaxoSmithKline. Additionally, GlaxoSmithKline and the primary healthcare service company, through the contract, confirmed that there were several safeguards in place to ensure that there could be no possibility of an inducement.

Specifically, the contract stipulated that all prescribers were able to deviate from the protocol to prescribe alternative therapies where clinically appropriate. The contract stipulated that a formulary committee, with distinct separation from the prescribers in the group, was required and affirmed that any medicine selected would be based upon the evidence, cost effectiveness and the

licensed indications. Given that these safeguards were in place and that the decision to place Avandamet on the protocol predated the relationship with GlaxoSmithKline the company firmly rejected any suggestion that this relationship constituted an inducement and a breach of Clause 18.1. Additionally, as this relationship specifically facilitated the primary healthcare service company's own diabetes service which benefited patients, GlaxoSmithKline refuted any breach of Clause 18.4.

GlaxoSmithKline's contract with the primary healthcare service company supported the running of the Diabetes Intermediate Service through funding to a maximum amount of £29,250. GlaxoSmithKline had no other involvement in the selection of the medicine for the management protocol and was not involved in any way in the management or provision of the service.

To ensure appropriately high ethical standards were maintained within this business-to-business relationship, the following detailed principles were stringently followed:

- The relationship was between GlaxoSmithKline and the primary healthcare service company and not with the individual prescribers forming part of the primary healthcare service company.
- The protocol was established by the primary healthcare service company, independently of discussions with GlaxoSmithKline and prior to discussions regarding the Diabetes HCP. GlaxoSmithKline understood that the protocol was in place prior to February 2007.
- The provision of funding for the Diabetes Intermediate Service was not conditional on the prescription of any product (clause 3.1 of the contract).
- The protocol was the responsibility of the primary healthcare service company. Responsibility for the management of individual patients, including prescription of medicines and implementation of appropriate treatment at all times remained with the GPs (clause 2.4 of the contract).
- The implementation of protocols was the sole responsibility of the primary healthcare service company. GlaxoSmithKline was not involved in protocol implementation.
- The creation of such protocols was intended to have an impact on the general patient population rather than determining prescription choice at an individual patient level. In this way the primary healthcare service company took a strategic view of the medicines and services provided to the patient population but left the final decision for the individual patient to the health professionals (clause 2.4 of the contract).
- GPs retained clinical freedom for any individual patients (clause 2.8 of the contract).
- The contract stipulated that where the primary healthcare service company decided to put a product on its protocol, this indicated to GP practices in its group that it considered the use of that product to be preferable to other products from the same therapy class having reviewed the product's licence, evidence and cost effectiveness (clause 2.2 of the contract).
- The primary healthcare service company confirmed that putting Avandamet on its protocol formed part of its business-related activities. The business-related activities were in relation to the general services and medicines provided to the population of patients forming part of the primary healthcare service company (clause 2.3 of the contract).
- The primary healthcare service company confirmed that there was an effective procedure in place to ensure that decisions related to the creation and content of its protocol were only made by personnel who had been duly authorised to make protocol-related decisions. In particular, the procedure required the following:
- At least half of the personnel who made the protocol decisions were non-prescribers.
- Prescribers who were authorised to make protocol-related decisions did not form the majority of prescribers within the primary healthcare service company (clause 2.3 of the contract).
- the primary healthcare service company confirmed that GlaxoSmithKline's medicines, including any product selected as first choice medicine, would only be used where appropriate and in accordance with local guidelines (clause 2.7 of the contract).

For the reasons stated above, GlaxoSmithKline was extremely confident that the Diabetes HCP did not form an inducement, provided a valuable service to medicine that was compatible with the stated aims of the NHS, MISG and the DoH guidance and benefited patient care. Thus it firmly denied any breach of Clauses 18.1, 18.4, 9.1 or 2.

GlaxoSmithKline further explained that having been made aware that the primary healthcare service company was implementing a diabetes service, discussions began to assess whether mutual benefits could be brought to all parties. The Diabetes HCP was formalised through a contract between GlaxoSmithKline and the primary healthcare service company. GlaxoSmithKline did not review or have input into the protocols of the primary healthcare service company and it neither had a copy, nor ever had one, of its diabetes protocols.

To ensure the Diabetes HCP delivered clear benefits to patients, the NHS and GlaxoSmithKline a monitoring document was created to set out responsibilities, timings, analysis required and the proposed measurements. The anticipated benefits to all parties were:

- Patients would benefit from improved and standardised continuity of care and thus improved clinical outcomes and an enhanced ability to benefit from better planned and delivered future healthcare.
- The primary healthcare service company would

benefit through improved healthcare planning, service delivery and patient care, by enhancing and standardising the primary healthcare service company's approach to chronic diseases and thus its ability to engage successfully in PBC.
- PBC would create the potential for appropriate use of medicines, including those of GlaxoSmithKline, in suitable patients and that would give GlaxoSmithKline the opportunity to develop a strong and positive working relationship with the primary healthcare service company with a view to further collaborations in the future.

The specific measurements that GlaxoSmithKline set out initially to monitor the project were:

- Patient clinical outcomes
- Referrals to diabetes clinic in secondary care
- Efficiency of service
- Patient feedback
- Adherence of practices to treatment protocol
- Secondary care emergency admissions
- Patient use of other healthcare resources

The Diabetes HCP was initially discussed with the primary healthcare service company in February 2007 by the strategic partnerships manager within GlaxoSmithKline who was based in head office and was responsible for looking at how the relationship between the pharmaceutical industry and the NHS could achieve common goals and how it should change to reflect the changes in the environment in line with the DoH's guidance and the ABPI's position on joint working. The discussions that took place between the strategic partnerships manager and the primary healthcare service company were not product specific and were focused on identifying a potential project to deliver improved benefits to patients in an open and transparent way.

The strategic partnerships manager was not a product-related role, it was not promotional or remunerated based on sales and reported into the Integrated Healthcare Department within the UK business. The first meeting in February was held between GlaxoSmithKline and the primary healthcare service company where the Diabetes HCP was discussed. GlaxoSmithKline understood that the primary healthcare service company had the protocol in place prior to February 2007 and Avandamet was already selected independently of GlaxoSmithKline as first choice medicine in its therapy class for the appropriate patient group.

Between February and September 2007 GlaxoSmithKline and the primary healthcare service company discussed the Diabetes HCP to develop the contract that would facilitate the implementation of the primary healthcare service company's Intermediate Service. GlaxoSmithKline agreed to support the enhanced diabetes intermediate service by co-funding the service to a maximum value of £29,250 for a six month period.

GlaxoSmithKline and the primary healthcare service company had joined together in partnership through the Diabetes HCP as there was a common agenda of improving the services offered to diabetes patients. This had the aim of improving patient outcomes through facilitating the primary healthcare service company's service provision and thus the appropriate use of medicines in this patient population to achieve diabetes control in a primary care setting. This should also reduce secondary care referrals. As such, all parties (patients, the primary healthcare service company and GlaxoSmithKline) stood to benefit from delivering better diabetes control in a transparent relationship that implemented a diabetes management protocol while protecting prescriber clinical freedom.

The Diabetes HCP was a contractual relationship where the roles, responsibilities and benefits were all clearly defined in an open and transparent way. The contract formalised the relationship between the primary healthcare service company and GlaxoSmithKline. The contract enabled both parties to understand the benefits to each and enabled GlaxoSmithKline to understand how its medicines were used within the primary healthcare service company. However, as stated in the contract, GPs would at all times retain clinical freedom to prescribe the most appropriate medicine for their patients. As previously stated, the protocol was defined by the primary healthcare service company independently of GlaxoSmithKline and prior to any conversations regarding the Diabetes HCP. The primary healthcare service company was responsible for the development of its own protocol, which GlaxoSmithKline understood took place in 2006. GlaxoSmithKline was not involved in the development of this protocol. GlaxoSmithKline understood that the protocol was developed by the primary healthcare service company in conjunction with the secondary care diabetes consultant from a hospital, a diabetes specialist nurse and a medicines management pharmacist in 2006.

GlaxoSmithKline was disappointed to receive this complaint as it believed it had worked to the highest ethical standards. It also had a procedure to enable employees to escalate their concerns internally and again, it was disappointed that this had not happened. The company had recently been significantly restructured which unfortunately resulted in the displacement of the DFA team; the complaint might be from an employee who had been affected by the restructure.

GlaxoSmithKline believed the Diabetes HCP was an ethical way of working. The partnership reflected the principles set out in the recent communication from the ABPI and the DoH 'Moving Beyond Sponsorship'. In addition, GlaxoSmithKline noted that a toolkit had been launched by the ABPI and the DoH on 5 March 2008 supporting joint working. GlaxoSmithKline believed that the Diabetes HCP was in line with the remit of this document to explore ways in which:

- The pharmaceutical industry could work with and

within the NHS, such that government objectives to improve the quality and value of NHS services, and the overall productivity of the system, could be achieved.
- Industry activities supported the operation of new NHS structures and processes, and industry skills were deployed appropriately.
- Innovative, clinical and cost effective solutions (both products and services) to address patients' health needs were embraced by the NHS and suitably rewarded and hence the UK's position as the slowest adopter of modern medicines was addressed.
- A more 'mature' relationship could be developed between the industry and the NHS (at both national and local levels) through joint working on areas of mutual interest and benefit.

For these reasons GlaxoSmithKline believed that the arrangements in this relationship were completely compatible with the ABPI's own principles, and it had strived to ensure that these and the principles of patient benefit were upheld.

Finally GlaxoSmithKline reiterated that it believed that it had not breached the Code with respect to Clauses 2, 9.1, 18.1 or 18.4 as alleged.

FURTHER RESPONSE

In response to a request from the Panel for further information GlaxoSmithKline emphasised the fact that the fundamental relationship established between GlaxoSmithKline and the primary healthcare service company was different in nature to that which it would have with prescribers. As set out above the Diabetes HCP aimed to bring clear and transparent benefits to patients, the NHS and GlaxoSmithKline by combining industry and NHS resources and expertise in the management of diabetes. The partnership was aligned with and responded to the government's agenda to treat more patients in the primary care environment and to achieve a sustainable improvement to the total healthcare economy.

Through the Diabetes HCP GlaxoSmithKline and the primary healthcare service company had formed a business-to-business relationship bound by a legal contract. The relationship enabled the primary healthcare service company to better manage its Diabetes Intermediate Service and thus the care of its diabetic patients according to its pre-existing protocol. The relationship was held between GlaxoSmithKline and two authorised representatives of the primary healthcare service company, the Managing Director and the Business Manager. GlaxoSmithKline firmly rejected any suggestion that this relationship was inappropriate or in breach of Clause 18.1.

It was important to emphasise that the wording of the contract underscored the principles of GlaxoSmithKline's ways of working with these groups. The contract specifically excluded practices or other healthcare providers which did not have a formal protocol process or PBC type capability. The contract required a distinct separation of the contract partners and prescribers, thus ensuring clinical prescribing freedom when necessary. These principles would not allow GlaxoSmithKline to enter into such a relationship where these criteria could not be fulfilled. As such only a small selection of PBC type providers would be suitable for such a relationship. By limiting the nature of the groups available for such a relationship and ensuring these safeguards were in place, GlaxoSmithKline was able to work specifically in this way within the parameters of the MISG and DoH guidance.

The primary healthcare service company and GlaxoSmithKline had successfully worked together for a number of years. In 2005, an integrated healthcare manager from GlaxoSmithKline became aware through the course of routine business that the primary healthcare service company was evolving and growing into a key customer group which was already engaged in PBC. A key focus of the group was to develop and improve the services provided to patients in its local area while expanding the remit of the practices in its group. GlaxoSmithKline understood that the primary healthcare service company had established protocols across numerous disease areas, including diabetes, as part of its standard ways of working. the primary healthcare service company in its discussions with GlaxoSmithKline recognised that there were likely to be benefits of working in partnership with the pharmaceutical industry as supported by the DoH, MISG and the ABPI.

In September 2005, the primary healthcare service company was keen to provide an improved Intermediate Diabetes Service with the vision that once this concept was able to prove its value to patient care pathways, it would be commissioned by a PCT. A GlaxoSmithKline integrated healthcare manager worked with the primary healthcare service company to help support and develop the first diabetes pilot project. The key members of the primary healthcare service company that were involved in the development and set up of this project were the Managing Director and the Business Manager. To support the primary healthcare service company's objectives, GlaxoSmithKline provided financial support to the pilot project commencing 1 November 2006 together with facilitation, education and training via a DFA to enable the primary healthcare service company to provide the Intermediate Diabetes Service. This support was entirely non promotional and did not relate to any products, but was solely related to diabetes.

The diabetes pilot project in 2006 was set up between GlaxoSmithKline and the primary healthcare service company to support the primary healthcare service company achieving the following goals:

- Meet its quality outcome framework (QOF)

targets and to provide improved diabetic care to patients.
- Provide a comprehensive diabetes service without referral to secondary care unless absolutely necessary
- Avoid use of a secondary care service
- Allow the practice and the PCT to make savings by reducing secondary care referrals and move routine management to primary care
- Allow proposed diabetes services to be recognised by the PCT as a locally enhanced service thus allowing other practices to refer in and create a revenue stream for the primary healthcare service company
- Allow practices to maximise GMS points within the clinical domain of diabetes.

As referred to above, GlaxoSmithKline supported the primary healthcare service company during the pilot phase of the Diabetes Intermediate Service. The support in this pilot phase involved financial support (£12,000) towards the provision of the primary healthcare service company employing a DSN, independently of GlaxoSmithKline, for two days a week over a 6 month period from 1 November 2006. GlaxoSmithKline had no input to the activities or objectives of the DSN. The DSN was to deliver a comprehensive diabetes service across the practices within the the primary healthcare service company group. Clinics were run by the DSN to review the appropriate patients and an HbA1c check was performed during the consultation. Lifestyle and dietary advice was also given as required. A DFA provided additional education and training to the group where necessary.

The support provided to the primary healthcare service company during the pilot phase in 2006 was non promotional. The project was initiated as a pilot project, as it was one of the first projects GlaxoSmithKline had undertaken with a customer to help achieve the goals of PBC.

GlaxoSmithKline was not involved in the creation or implementation of a diabetes protocol, and did not see or review the primary healthcare service company's protocol during this time.

In January 2007, while the pilot project was ongoing, GlaxoSmithKline and the primary healthcare service company discussed the potential for future partnership working. Present at the meeting was the Managing Director and Business Manager of the primary healthcare service company, and the Integrated Healthcare Manager, Regional Healthcare Manager (RHM), and the Strategic Partnerships Manager of GlaxoSmithKline. The primary healthcare service company was keen to continue providing the Diabetes Intermediate Service that had, as expected, been commissioned by the PCT, and to improve the service where possible. A meeting was scheduled for February 2007 to discuss how GlaxoSmithKline and the primary healthcare service company could work together in partnership on a different basis regarding the Diabetes Intermediate Service. The meeting in February 2007 was the first meeting where the primary healthcare service company and GlaxoSmithKline discussed and developed the Diabetes HCP. At this meeting the primary healthcare service company informed GlaxoSmithKline that it had a diabetes patient management protocol already in place, and this was in place as part of its normal patient management plans. The primary healthcare service company's protocol had existed before any conversations with GlaxoSmithKline regarding diabetes projects ie prior to September 2005. GlaxoSmithKline did not review or have input into the primary healthcare service company's protocols; it had never seen a copy of the protocols, until specifically requested to obtain a copy by the Authority. GlaxoSmithKline understood from the primary healthcare service company that Avandamet was named on its protocol as first choice medicine within class where appropriate. On receipt of a copy of the primary healthcare service company's protocol on 18 March 2008, GlaxoSmithKline found out for the first time that Avandamet was not specifically named on the primary healthcare service company's protocol. The protocol set out the use of a combination glitazone/metformin at the appropriate place, of which Avandamet would be one option.

As stated above, PBC groups, provider arms of PBC groups, such as the primary healthcare service company, PCTs, foundation trusts and private providers operated as businesses. They were often legal entities with formalised corporate structures in place. These groups had financial responsibility for the management of patient care in a locality. Within this, their remit was to purchase and deliver high quality care, including services and medicines to a patient population. Their roles and responsibilities (as with many health providers both within and outside the NHS) included the use of protocols for patient management and for the rational use of medicines. These were routinely employed to deliver a consistent standard of healthcare to consider the needs of the population. These needs were however different to those of the individual prescribers and health professionals who were specifically considering the needs of individual patients within the protocol and formulary framework.

The relationship between GlaxoSmithKline and the primary healthcare service company through the Diabetes HCP was at a business-to-business level with the directors who managed the company. In this relationship the roles and responsibilities were clearly defined according to an agreed contract. GlaxoSmithKline's relationship was not with individual prescribers or practices, therefore a clear separation between the business-related activities of the organisation and the prescribing activities of individual health professionals was maintained. Given this explicit and transparent separation, GlaxoSmithKline believed that this relationship was compatible with the stated aims of the MISG and the DoH guidance regarding joint working.

GlaxoSmithKline did not know about the formal protocol review that took place in March 2007 until it clarified the chronology of events with the primary healthcare service company to enable the company to respond to this complaint. The primary healthcare service company confirmed that there was no amendment to the positioning of Avandamet on its protocol during the review that took place in March 2007. GlaxoSmithKline did not have any involvement in the creation or implementation of a diabetes protocol during this time.

GlaxoSmithKline provided a document which set out the chronology of its relationship with the primary healthcare service company, what was agreed when and how the protocol changed over time. A copy of the diabetes protocol was also provided.

As GlaxoSmithKline had not previously seen the protocol, nor had input into it, it had never made any contemporaneous comments upon it. Having now, as part of the Authority's investigation into this case, seen a copy of the protocol it noted that the position of glitazones and their fixed dose combination with metformin, was consistent with NICE guidance and generally accepted therapeutic principles, based on evidence based medicine.

GlaxoSmithKline understood from the primary healthcare service company that its protocol had been in place for a number of years. As described above, the protocol was established before GlaxoSmithKline's involvement in the pilot Diabetes Intermediate Service in 2006 and the Diabetes HCP in 2007. The primary healthcare service company reviewed its protocol in March 2007 without any involvement from GlaxoSmithKline and to GlaxoSmithKline's knowledge there was no amendment to the positioning of Avandamet on the primary healthcare service company's protocol during 2006 and 2007.

The protocol review that took place by the primary healthcare service company in March 2007 was a standard review, independent of any relationship with GlaxoSmithKline.

GlaxoSmithKline understood, until receipt of the protocol on 18 March 2008, that Avandamet was specifically named on the protocol. However, the primary healthcare service company had subsequently clarified that the terminology included on its protocol at this specific stage of treatment was in fact the use of a combination drug; Avandamet would fall into this classification. Avandamet was specifically named in the contract as GlaxoSmithKline understood that the primary healthcare service company's established protocol specifically named Avandamet in the appropriate place. This had proven not to be the case, however Avandamet would fit into the combination of metformin and a glitazone as named on the protocol.

GlaxoSmithKline submitted that its sponsorship was not dependent upon the primary healthcare service company's decision to place Avandamet on the protocol. The primary healthcare service company's protocol had already been finalised prior to any conversations regarding the diabetes HCP. The protocol was the primary healthcare service company's property and responsibility and was able to be reviewed at any time by the primary healthcare service company as deemed necessary. A copy of the protocol that was signed off in March 2007 was provided. The primary healthcare service company confirmed that this was the latest protocol approved.

The responsibility for the implementation and communication of the protocol was the primary healthcare service company's. This was referred to in the Diabetes HCP contract between the primary healthcare service company and GlaxoSmithKline, clause 2.4 as follows:

- Responsibility for the management of individual patients, including prescription of medicines and implementation of appropriate treatment shall at all times remain with the GPs at the practices comprised in the Group, the primary healthcare service company.

GlaxoSmithKline had had no involvement in the creation, training, communication or implementation of the protocol within the the primary healthcare service company group.

A key principle behind the Diabetes HCP was that the protocol was owned and defined by the primary healthcare service company. The communication and implementation of a protocol was part of the normal business activities of the primary healthcare service company in the same way as a hospital would manage a formulary.

GlaxoSmithKline explained that the request to measure the adherence of practices to the treatment protocol was made by the primary healthcare service company to understand how protocols and treatment pathways were being followed within the group. GlaxoSmithKline understood that this was part of its standard audit procedures. The primary healthcare service company was not required to assess the number of Avandamet prescriptions or for this information to be shared with GlaxoSmithKline. No payment or activity was contingent on the extent of prescription of any medicine

GlaxoSmithKline explained that the Diabetes Intermediate Service and the Diabetes HPC were not the same. The Diabetes Intermediate Service was the overall service run by the primary healthcare service company. The Diabetes HPC described the contractual relationship between GlaxoSmithKline and The primary healthcare service company. As part of the Diabetes HCP, GlaxoSmithKline agreed to financially support the primary healthcare service company to the amount of £29,250 to support its Diabetes Intermediate Service.

PANEL RULING

The Panel noted GlaxoSmithKline's comments about joint working between the industry and the NHS. Such activities were not prohibited by the Code providing all the arrangements complied with it, in particular Clauses 18.1 and 18.4.

The Panel noted GlaxoSmithKline's submission regarding the arrangements to ensure compliance with the Code. The Panel considered that in general arrangements that increased the potential pool of treated patients were likely to be acceptable. Arrangements that increased the prescribing of one specific product were likely to be unacceptable. The Panel accepted that a service that improved clinical outcomes, standardized continuity of care and reduced the number of secondary care referrals, all aims of the service at issue, would enhance patient care and benefit the NHS.

The Panel noted that the complaint had been prompted by a voicemail message sent from within GlaxoSmithKline. The voicemail referred to the company's business relationship with the primary healthcare service company whereby GlaxoSmithKline had agreed to help The primary healthcare service company achieve its objective of reducing the number of diabetic patients referred to secondary care by deploying a specialist team, led by a consultant diabetologist, in the primary care setting. It was stated in the voicemail that '… GlaxoSmithKline has contributed to the cost of running the service, while [the primary healthcare service company] has agreed to select Avandamet as first medicine in its class on its diabetes protocol for appropriate patients. This is a contractual agreement between two commercial organisations'. The complainant was concerned that GlaxoSmithKline's sponsorship of the service was dependent upon the inclusion of Avandamet on the protocol.

The contract that existed between GlaxoSmithKline and The primary healthcare service company was dated 3 September 2007 and headed 'Enhanced PBC Service – Diabetes Pilot Project'. It was stated in an appendix to the contract that in 2006 GlaxoSmithKline had helped create a new diabetes service by providing some of the funding and identifying a suitable consultant diabetologist and diabetic specialist nurse. The primary healthcare service company now wanted to maintain and improve this service the aim of which would be to manage optimally all aspects of diabetes in primary care, only referring patients into secondary care when absolutely necessary. Point 9 of the appendix stated 'The proposal is for GSK to help [the primary healthcare service company] with the creation of this enhanced Diabetes Intermediate Service by co-funding it'. It was stated that staff forming part of the specialist team would be employees or contractors of the primary healthcare service company; none of the staff would be employees of GlaxoSmithKline.

According to its website the primary healthcare service company was a private limited company and a provider of primary healthcare services.

The Panel noted guidance issued by the DoH in January 2008 on joint working between the NHS and the pharmaceutical industry defined joint working as:

'Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme…'.

The Panel noted that GlaxoSmithKline had referred to this definition albeit one that was published some four months after the contract with the primary healthcare service company had been signed. The Panel noted that GlaxoSmithKline had helped the primary healthcare service company to develop its first diabetes pilot project by providing financial support, facilitation and training via a Diabetes First Associate. In the Panel's view, however, the relationship between the primary healthcare service company and GlaxoSmithKline in the service now at issue did not appear to be one whereby the two organisations had pooled skills, experience and/or resources; it appeared that GlaxoSmithKline had acted simply to co-fund, or sponsor, the primary healthcare service company's diabetes service. In that regard the Panel noted GlaxoSmithKline's submission that its contract with the primary healthcare service company supported the running of the Diabetes Intermediate Service through funding to a maximum of £29,250 and that the company had no other involvement in the selection of the medicine for the management protocol and was not involved in any way in the management or provision of the service.

The Panel noted that GlaxoSmithKline had submitted that its relationship with the primary healthcare service company was at a business-to-business level and not with individual prescribers. GlaxoSmithKline described this as an explicit and transparent separation. In the Panel's view, however, GlaxoSmithKline was in effect working with a third party which it knew would influence the prescribing activities of individual doctors.

The Panel noted that the contract between the primary healthcare service company and GlaxoSmithKline set out the roles and responsibilities of each party. Paragraph 3.1 of the contract stated 'This project is sponsored by GSK. As a consequence of [the primary healthcare service company's] decision to place GSK's product on [the protocol] in accordance with paragraph 2.6 above,

GSK has agreed to provide funding for this service: provisions of such funding is not conditional on the prescription of that product'. Other paragraphs defining GlaxoSmithKline's involvement related to the payment of the agreed funding, the use of any data provided to the company by the primary healthcare service company and the fact that GlaxoSmithKline would comply with best practice to include codes of practice, relevant laws and guidelines on confidentiality and data protection.

The contract between the primary healthcare service company and GlaxoSmithKline stated, at paragraph 2.6 'Subject to paragraphs 2.7 and 2.8 below, [the primary healthcare service company] has agreed to select AVANDAMET ("the product") as a first choice medicine in its therapy class for the appropriate patient group on the Protocol ("First Choice Medicine"). Such selection by [the primary healthcare service company] shall include all considerations as per paragraph 2.2 above'. Paragraph 2.2 stated that the choice and use of medicines within a protocol was based upon the medicine's marketing authorization, an up-to-date review of the available evidence and its cost effectiveness. The protocol was for use by all the primary healthcare service company practices. It was, presumably, paragraph 2.6 which had led to the statement in the voicemail that '[the primary healthcare service company] has agreed to select Avandamet as first medicine in its class on its diabetes protocol …'.

Paragraphs 2.7 and 2.8 of the contract made it clear that GlaxoSmithKline's medicines, including Avandamet, would only be used where appropriate and in accordance with local guidelines. Further, GPs in the group would retain clinical freedom for any individual patients for whom, in the GP's opinion, use of Avandamet was inappropriate. Paragraph 2.16 stated that GlaxoSmithKline would be provided with anonymised data relating to prescribing and outpatient outcomes.

The Panel noted that in response to a request for further information GlaxoSmithKline provided a copy of the diabetes protocol dated March 2007 and due for review by March 2008, which it submitted was the first time the company had seen it. Under a heading of 'Glycaemic Control' for type 2 diabetics it was stated that step 2 treatment, for all patients with a body mass index of 25 or more, should be:

'Add Glitazone to metformin
- 1st line: pioglitazone
- 2nd line: rosiglitazone

Increase dose up gradually as required to maximum.

Glitazones are slow acting drug so results will not be noticeable immediately; reduction of blood glucose will happen over 4 - 6 weeks.

If there are compliance problems the combination tablets of Glitazone/metformin may be used…'

It thus appeared that the protocol and paragraphs 2.6 and 3.1 of the contract were inconsistent with one another. In the protocol rosiglitazone, the glitazone in Avandamet, was stated to be the second line glitazone and in any event the combination tablets ie Avandamet, were only to be used if there were compliance problems. Given the protocol as it existed (effective from March 2007 and due for review by March 2008) the Panel queried why the contract was signed in September 2007 containing paragraph 2.6 specifically referring to Avandamet as a first choice medicine in its therapy class. The protocol referred to products by generic name only. The contract had been signed by senior managers in both GlaxoSmithKline and the primary healthcare service company. One of GlaxoSmithKline's signatories appeared to be responsible for the voicemail to the complainant.

The Panel considered that, notwithstanding the protocol, paragraph 3.1 of the contract signed by GlaxoSmithKline in effect stated that the company's funding of the diabetes service was dependent upon the inclusion of Avandamet, as a named medicine, on the protocol. This was also the impression given in the voicemail. The Panel noted that the provision of medical and educational goods and services must not be linked to any medicine. In that regard the Panel considered that the diabetes service as described in the voicemail and in the contract was inappropriate. A breach of Clause 18.4 of the Code was ruled. High standards had not been maintained. A breach of Clause 9.1 was ruled. These rulings were appealed.

With regard to whether or not the arrangements amounted to an inducement to members of the health professions or administrative staff to prescribe, supply, administer, recommend, buy or sell Avandamet, the Panel noted that there was no gift, benefit in kind or pecuniary advantage to the actual prescribers. However the prescribers, as employees of the primary healthcare service company, would be obliged to follow the protocol. As far as GlaxoSmithKline was concerned the effect of the arrangements was that a payment had been made to a private company such that Avandamet was recommended. The Panel was concerned about the arrangements but after much consideration decided that, on balance, the circumstances of providing an inducement to the primary healthcare service company did not amount to a breach of Clause 18.1 of the Code and ruled accordingly.

The Panel was concerned that the diabetes service was seen by some in GlaxoSmithKline as being linked to the use of Avandamet as first medicine in its class. The Panel noted that, given the content of the protocol and unbeknown to GlaxoSmithKline, as operated, the diabetes service was not linked to the use of Avandamet. The Panel thus considered that on balance, taking all the circumstances into account, GlaxoSmithKline had not brought discredit upon, or reduced confidence in, the pharmaceutical industry. No breach of Clause 2 was ruled.

APPEAL BY GLAXOSMITHKLINE

GlaxoSmithKline submitted that the evolving structural changes within the NHS had given rise to a number of new customer groups for the pharmaceutical industry including PCTs, PBC groups, private providers and Foundation Trusts. These groups purchased healthcare rather than simply delivered it and they might also be businesses. Hence, as recognised by the ABPI, the DoH and these groups themselves they required a different type of relationship to traditional health practitioners with the pharmaceutical industry to effectively deliver healthcare in an efficient and ethical manner. The primary healthcare service company was an example of a new, specific customer group, ie a limited company which operated to deliver a wide range of services to practices under the contractual opportunities offered by PBC.

GlaxoSmithKline submitted that the fundamental premise of its appeal was that the diabetes care package was a corporate agreement between itself and the primary healthcare service company. The partnership was transparent, of high ethical standard and importantly was a collaboration that had patient benefit as the prime objective for both parties. The partnership between GlaxoSmithKline and the primary healthcare service company set out how the pharmaceutical industry and the NHS could work together to deliver improved patient outcomes within this new and changing environment.

GlaxoSmithKline submitted that the principles underpinning the diabetes care package were fully ethical and appropriate and were not in breach of Clauses 9.1 and 18.4 of the Code.

Background for the Diabetes HCP

GlaxoSmithKline submitted that the Diabetes HCP was established with response to four key factors:

- The emergence of new, specific customer groups within the NHS
- The requirement for a different type of working relationship between these customer groups and the pharmaceutical industry
- Guidance from the DoH and other key groups regarding joint working
- To demonstrate the value that joint working could bring to patients through improving patient outcomes and delivering better patient focused services.

Joint working between the NHS and the pharmaceutical industry

GlaxoSmithKline submitted that the Ministerial Industry Strategy Group (MISG) was a joint industry and DoH high-level group bringing together government and pharmaceutical industry representatives as part of the follow-up to the implementation of the Pharmaceutical Industry Competitiveness Task Force (PICTF) recommendations. MISG was set up following a conclusion in the March 2001 PICTF report that a new high-level group was required to take the government industry relationship forward at a strategic level. MISG was co-chaired by a minister of health and a senior industry executive and included governmental, industry and ABPI representation, including the Director General of the ABPI. Hence, the principles and objectives of the MISG were supported by the ABPI. The MISG had developed an agreed vision of partnership which stated:

'The industry can bring more than just medicines to the NHS and the patients it serves in the form of skills and expertise to support top quality and productive services. For this to happen, however, a more "mature" relationship has to be developed between the industry and the NHS founded on mutual respect and trust and demonstrated through successful working on areas of mutual interest and benefit.'

Further guidance from the DoH supporting joint working between the NHS and the pharmaceutical industry stated:

'Joint working between the pharmaceutical industry and the NHS must be for the benefit of patients or the NHS and preserve patient care. Any joint working between the NHS and the pharmaceutical industry should be conducted in an open and transparent manner. All such activities, if properly managed, should be of mutual benefit, with the principal beneficiary being the patient. The length of the arrangement, the potential implications for patients and the NHS, together with the perceived benefits for all parties, should be clearly outlined before entering into any joint working.

For the purpose of this guidance, joint working is defined as follows:

Situations where, for the benefit of patients, organisations pool skills, experience and/or resources for the joint development and implementation of patient centred projects and share a commitment to successful delivery. Joint working agreements and management arrangements are conducted in an open and transparent manner. Joint working differs from sponsorship, where pharmaceutical companies simply provide funds for a specific event or work programme.'

GlaxoSmithKline submitted that there had been considerable guidance issued recently encouraging joint working and recognising the considerable benefits, especially to patients, that joint working could bring. Examples of this guidance were:

- DoH Best Practice Guidance on Joint Working between the NHS and Pharmaceutical Industry and Other Relevant Commercial Organisations
- ABPI, Moving Beyond Sponsorship
- ABPI, Moving Beyond Sponsorship, Joint

Working Between the NHS and Pharmaceutical Industry Toolkit

Given that this was a relatively new area of working, the guidance from MISG had been important in how GlaxoSmithKline had set up this relationship, given that the Code did not explicitly address these types of arrangements, but dealt in general terms with medical and educational goods and services. GlaxoSmithKline and other member companies were willing to ensure that the revised Code made provision for appropriate working between these bodies and the industry to ensure that patient benefit remained at the centre of the relationship. A work stream had been established by the ABPI recognised that the current Code did not explicitly reflect these new principles that needed to be established in joint working between the NHS and the pharmaceutical industry. Nevertheless GlaxoSmithKline had operated within the current guidance of the Code, MISG and DoH.

The emergence of new customer groups within the NHS

GlaxoSmithKline submitted that PBC groups, provider arms of PBC groups, such as the primary healthcare service company, PCTs, Foundation Trusts and private providers operated as businesses. They were often legal entities with formalised corporate structures in place. These groups had financial responsibility for the management of patient care in a locality. Within this, their remit was to purchase and deliver high quality care, including services and medicines to a patient population. Their roles and responsibilities (as with many health providers both within and outside the NHS) included the use of protocols for patient management including the rational use of medicines. These were routinely employed to deliver a consistent standard of healthcare according to the needs of the population. These needs were however different to those of the individual prescribers and health professionals who specifically considered the needs of individual patients within the protocol and formulary framework.

Protocols and pathways played an important role in patient management. This had become increasingly so with the introduction of PBC and World Class Commissioning where health professionals formed groups and were therefore responsible for the management of patients across larger patient populations. Their approach to disease management had become more strategic and the implementation of protocols assisted in this. In addition, with the government's goal of providing more accessible healthcare within primary care, pathways and services were being reviewed.

The role of a formulary committee within a PBC group or provider arm of a PBC group was similar to that within a hospital environment. The formulary committee, with distinct separation from the prescribers in the group, was required to independently select an appropriate medicine based upon the evidence, cost effectiveness and the licensed indications. The role of a hospital formulary was to make decisions on behalf of the hospital and looked strategically at the medicines that would provide the best outcomes for patients. The pharmaceutical industry would provide a formulary committee with all the information about their medicines required to enable it to make an informed decision. This was distinct from influencing individual prescribers. In a similar way, the role of the formulary committee had transitioned into primary care through the emergence of PBC groups, provider arms and PCTs. A different type of relationship was therefore required between the pharmaceutical industry and these customer groups to reflect their changing structure and needs. The primary healthcare service company was an example of a new and specific customer group which had a common agenda with GlaxoSmithKline of improving the services and medicines provided to patients with type II diabetes.

Background to the primary healthcare service company

GlaxoSmithKline submitted that the primary healthcare service company was a limited company which delivered a wide range of services to practices under the contractual opportunities offered by PBC. GlaxoSmithKline referred to a description of the primary healthcare service company as it appeared on that company's website.

GlaxoSmithKline submitted that as the primary healthcare service company operated across a large patient population, the Diabetes HCP was established as a mechanism of delivering improved services and medicines to its diabetic patients.

The benefits of joint working between the NHS and the pharmaceutical industry

GlaxoSmithKline submitted that the principles established as part of the HCP were consistent with the points highlighted below from the Joint Working Toolkit, supported by the ABPI:

- Shared vision: Each party must have a mutually shared vision of the aims and outcomes of any arrangement that underpinned all aspects of working together.
- Equity: Recognition, backed by behaviour, that each party had the right to be at the table and their contributions valued.
- Transparency: Openness and honesty (a precondition to trust); access to and sharing of information.
- Mutual benefit: Each party should be entitled to benefit from the arrangement – ideally working to specific benefits for each party as well as the common benefits to all.
- Respect: Respect for the other parties and for their ability to add value.

The anticipated benefits to all parties were as follows:

- Patients would benefit from improved and standardised continuity of the care provided, and thus improved clinical outcomes and an enhanced ability to benefit from better planned and delivered future healthcare.
- The primary healthcare service company would benefit through improved healthcare planning, service delivery and patient care, by enhancing and standardising the primary healthcare service company's approach to chronic diseases and thus its ability to engage successfully in PBC. The primary healthcare service company would also benefit from the expertise provided by GlaxoSmithKline through resource, education and training within the diabetes disease area to assist in the implementation of its Diabetes Intermediate Service.
- PBC would create the potential for appropriate use of medicines, including GlaxoSmithKline's, in suitable patients and that this would give GlaxoSmithKline the opportunity to develop a strong and positive working relationship with the the primary healthcare service company with a view to further collaborations in the future.

As a commercial organisation, GlaxoSmithKline needed to ensure that its medicines had maximum impact on patients' lives. This meant identifying the right patient to get the right treatment to get the right outcome and was not a simple equation of influencing prescriptions as alleged in the Panel ruling. GlaxoSmithKline aimed to partner with such organisations for long term collaborations that delivered the joint benefits to all parties as outlined above. This meant establishing a long term beneficial relationship and not a short term prescription goal. This could be seen in the structure of the contract where there was no link to the number of prescriptions of GlaxoSmithKline products required for the contract to proceed.

GlaxoSmithKline submitted that it was highly ethical to work with groups such as the primary healthcare service company which had already, independently agreed its protocol. This removed the risk of inducement to prescribe at individual prescribing level and influencing the protocol positioning of medicines. This was supported by the rationale set out in clause 2.2 of the contract. the primary healthcare service company, already with a GlaxoSmithKline medicine in a position on the protocol, was seen as a suitable partner to establish the principles of joint working and benefits whilst ensuring appropriate safeguards were in place. Without those safeguards GlaxoSmithKline would not have entered into the contract.

The Diabetes HCP

The relationship between GlaxoSmithKline and the primary healthcare service company was at a business-to-business level with those directors who managed the company. In this relationship the roles and responsibilities were clearly defined according to an agreed contract. The relationship was held between GlaxoSmithKline and the Managing Director and the Business Manager of the primary healthcare service company; it was not with individual prescribers or practices, therefore a clear separation between the business related activities of the organisation and the prescriber's activities professionals was maintained.

GlaxoSmithKline noted that the wording of the contract underscored the principles of its ways of working with these groups. The requirements of the contract specifically excluded practices or other healthcare providers who did not have a formal protocol process, specifically constituted formulary committee/group or PBC type capability. The contract required a distinct separation of the contract partners and prescribers, thus ensuring clinical prescribing freedom at all times. These principles would not allow GlaxoSmithKline to enter into such a relationship where these criteria could not be fulfilled. As such only a small selection of PBC type providers would be suitable for such a relationship. By limiting the nature of the groups available for such a relationship and ensuring these safeguards were in place, GlaxoSmithKline was able to work specifically in this way within the parameters of the MISG and DoH guidance.
With reference to clause 3.1 of the contract, as a consequence of the decision to place GlaxoSmithKline's product on the protocol in accordance with clause 2.6 above, GlaxoSmithKline had agreed to fund this service; such funding was not conditional on the prescription of that product. This was explained in further detail below:

- The protocol was established by the primary healthcare service company, independently of any discussions with GlaxoSmithKline and prior to the discussions regarding the Diabetes HCP.
- Avandamet should be used as first choice medicine within its class where appropriate.
- Inclusion of a product onto a protocol should be based upon the medicine's licence, an up-to-date review of the evidence available and its cost effectiveness in the patient group in question. These principles must be adhered to in the selection of any particular medicine for inclusion in a protocol (clause 2.2 of the contract). GlaxoSmithKline noted that the positioning described was consistent with guidance from the National Institute of health and Clinical Excellence (NICE).
- Treatment decisions should be determined in accordance with licence, indication, guidelines and also by the individual prescriber.

In addition, to ensure appropriate high ethical standards were maintained within this business to business relationship, the following detailed principles were stringently followed:

- The relationship was between GlaxoSmithKline and the primary healthcare service company and

not with individual prescribers forming part of the primary healthcare service company.
- The funding of the Diabetes Intermediate Service was not conditional on the prescription of any product (clause 3.1 of the contract).
- Responsibility for the management of individual patients, including prescription of medicines and implementation of appropriate treatment at all times remained with the GPs at the practices within the primary healthcare service company (clause 2.4 of the contract).
- The creation of such protocols was intended to have an impact on the general patient population rather than determining prescription choice at an individual patient level. In this way the primary healthcare service company could take a strategic view of the medicines and services provided to the patient population which left the final decision for the individual patient to the prescriber (clause 2.4 of the contract).
- GPs within the primary healthcare service company retained clinical freedom for any individual patients (clause 2.8 of the contract).
- The primary healthcare service company confirmed that the selection of Avandamet to appear on its protocol formed part of its business related activities. The business related activities were in relation to the general services and medicines provided to the population of patients forming part of the the primary healthcare service company (clause 2.3 of the contract).
- The primary healthcare service company confirmed that there was an effective procedure in place to ensure that decisions related to the creation and content of its protocol were only made by those who had been authorised to make protocol related decisions. In particular, the procedure required that:
  - At least half of those who made the protocol decisions were non-prescribers
  - Prescribers who were authorised to make protocol related decisions did not form the majority of prescribers within the primary healthcare service company (clause 2.3 of the contract).

For the reasons stated above, GlaxoSmithKline was confident that the Diabetes HCP did not form an inducement to prescribe but provided a valuable service to medicine of mutual benefit to all parties that was compatible with the stated aims of the NHS, MISG and the DoH guidance and benefited patient care. Thus GlaxoSmithKline submitted that this agreement was neither in breach of Clauses 18.4 nor 9.1.

Response to the specific Panel comments

GlaxoSmithKline noted that in the Panel's view the relationship between the primary healthcare service company and GlaxoSmithKline in the services now as issue did not appear to be one whereby the two organisations had pooled skills, experiences and/or resources; it appeared that GlaxoSmithKline had acted simply to co-fund, or sponsor, the primary healthcare service company's diabetes service.

GlaxoSmithKline submitted that the relationship between it and the primary healthcare service company had been ongoing for several years. In September 2005, the primary healthcare service company was keen to provide an improved intermediate diabetes service with the vision that once this concept was able to prove its value to patient care pathways, the service would be commissioned by the PCT. GlaxoSmithKline through its local Integrated Healthcare Manager worked with the primary healthcare service company to help support and develop the primary healthcare service company's first diabetes pilot project.

During the pilot phase of the Diabetes Intermediate Service in 2006 GlaxoSmithKline supported the primary healthcare service company through education, training, resource and expertise. A key focus in this pilot phase was to up skill the health professionals within the primary healthcare service company to enable a high quality service to be delivered. GlaxoSmithKline provided financial support to the primary healthcare service company's pilot project together with facilitation, education and training via a GlaxoSmithKline employed Diabetes First Associate. This support was entirely non-promotional and did not relate to any products, but was solely related to the diabetes disease area. The support provided in the diabetes pilot project in 2006 was set up to achieve the following goals:

- Meet their quality and outcomes framework (QOF) targets and to provide improved diabetic care to their patients
- Provide a comprehensive diabetes service to all diabetics without referral to secondary care unless absolutely necessary
- Allow the practice and the PCT to make savings and move 'routine' management to primary care
- Allow proposed diabetes services to be recognised by the PCT as a locally enhanced service thus allowing other practices to refer in and creating a revenue stream for the primary healthcare service company

In 2007, GlaxoSmithKline entered into the Diabetes HCP with the primary healthcare service company. The relationship was of a balanced nature where both parties shared experience, skills and resource to enable the Diabetes Intermediate Service, run by the primary healthcare service company, to be implemented and hence deliver improved benefits to patients. The support provided to the primary healthcare service company had changed over the last few years as its expertise and needs had evolved. GlaxoSmithKline had considerable expertise in this disease area through significant investment in the research and development of medicines. The ability to share this expertise through collaborations with customers such as the primary healthcare service company was key in delivering improved benefits to patients.

The Diabetes HCP differed from sponsorship, where

funding was provided for a specific event or programme. While the primary healthcare service company provided the underpinning service, GlaxoSmithKline provided a mix of resource and expertise as follows to enable the Diabetes HCP to be successfully implemented.

- Education and training
  - Education and training sessions for clinical staff via the GlaxoSmithKline employed Diabetes First Associate and through support of the the primary healthcare service company monthly meeting
  - Needs assessment of training requirements for Diabetes Specialist Nurses followed by delivery of applicable training modules
  - Data and education about the appropriate use of GlaxoSmithKline's medicines
  - Provision of appropriate clinical data
  - Facilitation of knowledge and best practice sharing
  - Business support through expertise on PBC and the changing requirements within healthcare
  - Support provided by the National Pharmacy Advisor within GlaxoSmithKline to help the primary healthcare service company with its pharmacy objectives.

- Data analysis and review
  - Detailed Hospital Episode Statistics (HES) data analysis was performed in 2007 on the 2005/2006 data to identify and prioritise opportunities for potential savings and for redesign of patient care in line with the DoH agenda. HES data provided groups with a clear and concise overview of their use of hospital services
  - GlaxoSmithKline personalised and tailored the support to help optimise the business opportunities for modelling future services

- Health outcomes information and expertise
  - IT support for a group audit on the identification of high risk patients
  - During the HCP, support was provided to the the primary healthcare service company team to extract and measure clinical outcomes
  - Measurement of efficacy of service through patient and practice surveys
  - Changes to secondary care emergency admissions through bespoke HES data analysis is to be performed on completion of the project

- Financial support for the Diabetes Specialist Nurse

- Communication and skills training
  - GlaxoSmithKline provided a workshop to support communication within the primary healthcare service company and also to help communication with other stakeholders such as the PCT.

GlaxoSmithKline reiterated that it was not involved in the training and implementation of the primary healthcare service company protocol or the specific diabetes training forming part of the Diabetes Intermediate Service. However, over the last few years GlaxoSmithKline continued to provide the primary healthcare service company with the above resource and expertise to enhance its Intermediate Service, outside of the Diabetes HCP contract, via the appropriate non-promotional or promotional staff in accordance with the principles of the Code.

GlaxoSmithKline submitted that it had demonstrated that its role in the pilot phase and through the Diabetes HCP was significantly more than funding and it was integral to the success of delivering the improved service to patients. As such GlaxoSmithKline respectfully disagreed with the Panel's interpretation and ruling on this point.

GlaxoSmithKline further noted that the Panel's view was that GlaxoSmithKline was in effect working with a third party which it knew would influence the prescribing activities of individual doctors. GlaxoSmithKline submitted that a key principle within the Diabetes HCP was that all health professionals retained clinical freedom to prescribe the medicine that was in the best interest of individual patients (clause 2.8 of the contract). In addition, the protocol had already been established and implemented by the primary healthcare service company independently of GlaxoSmithKline prior to the Diabetes HCP commencing. Therefore, responsibility for implementation of the protocol and influence over prescribing lay with the primary healthcare service company only.

The relationship between GlaxoSmithKline and the primary healthcare service company was at a business-to-business level and therefore it was not able to influence the individual doctors. The contract between GlaxoSmithKline and the primary healthcare service company stipulated numerous safeguards as described in detail above to ensure this was enforced. This included responsibility for the relationship with GlaxoSmithKline sitting with a combination of business personnel and health professionals and also the requirement for health professionals to retain clinical freedom and the ability to prescribe the medicine that was in the best interest of patients. Again, for these reasons GlaxoSmithKline respectfully disagreed with the Panel's ruling on this point.

GlaxoSmithKline noted that the Panel had noted that the provision of medical and educational goods and services must not be linked to any medicine. In that regard, the Panel considered that the diabetes services as described in the voicemail and the contract was inappropriate in breach of Clause 18.4 of the Code. The Panel had also considered that high standards had not been maintained in breach of Clause 9.1. GlaxoSmithKline submitted that the description of the Diabetes HCP and associated contract was in line with the MISG, DoH and ABPI guidance regarding joint working by setting out clear roles, responsibilities and the benefits to all

parties in a formal and transparent way.

Although a GlaxoSmithKline medicine was stipulated within the contract, freedom to prescribe the most appropriate medicine for the patient was maintained as a guiding principle and also clearly articulated in the contract. The protocol was established before the Diabetes HCP started and the protocol referred to generic name only. Nowhere in the contract was GlaxoSmithKline's participation linked to prescription volumes. Given the strategic nature of the relationship and the safeguards in place, GlaxoSmithKline disagreed with the Panel's interpretation and subsequent rulings and submitted that the mention of Avandamet was completely appropriate and transparent as required by the MISG principles. As such GlaxoSmithKline denied a breach of Clause 18.4. GlaxoSmithKline had striven to adopt and maintain the highest standards and had engaged senior managers who were aware of the environmental considerations and the Code in setting up these relationships and refuted the breach of Clause 9.1.

In summary, GlaxoSmithKline submitted that it had operated in a transparent, open way to the highest of ethical standards, in accordance with the guidance issued from the MISG, DoH and ABPI. GlaxoSmithKline's overarching principle was to deliver improved benefits to patients through joint working. GlaxoSmithKline and the primary healthcare service company had worked together, sharing expertise and resource to enable the Diabetes Intermediate Service to be delivered in the best possible way. For the reasons stated above, GlaxoSmithKline considered that the Diabetes HCP was not in breach of Clause 18.4 and 9.1 and had maintained the high standards of the industry.

GlaxoSmithKline noted the precedent that might be set if the Panel's rulings were upheld. With the importance of these new relationships being underpinned by the agreed MISG position, GlaxoSmithKline was concerned that the precedent maybe at a variance with the strategic direction regarding joint working between the NHS and the pharmaceutical industry. It was for this reason, as well as the fact that all of GlaxoSmithKline's dealings had been ethical and appropriate that it appealed the Panel's rulings.

APPEAL BOARD RULING

The Appeal Board noted GlaxoSmithKline's comments about joint working between the industry and the NHS. Such activities were not prohibited by the Code providing all the arrangements complied with it. The Appeal Board accepted that a service that improved clinical outcomes in diabetes, standardized continuity of care and reduced the number of secondary care referrals, all aims of the service at issue, would enhance patient care and benefit the NHS.

The Appeal Board noted GlaxoSmithKline's concerns about the adverse implications of this case on the future of the joint working initiative should the Panel's rulings be upheld. The Appeal Board disagreed; each case turned on its own merits.

The Appeal Board noted that the question to be answered was 'Did GlaxoSmithKline support the Diabetes HCP in return for Avandamet being named on the group's treatment protocol?' The Appeal Board noted inconsistencies between the voicemail message, which had prompted the complaint, the written contract between GlaxoSmithKline and the primary healthcare service company, and the protocol employed by the primary healthcare service company for the treatment of type 2 diabetes. In that regard the Appeal Board considered that it had to make its ruling on the service as described by GlaxoSmithKline in its voicemail and in the contract which it signed, as opposed to the protocol.

The Appeal Board noted that the voicemail message stated that '… GlaxoSmithKline has contributed to the cost of running of the service, while [the primary healthcare service company] has agreed to select Avandamet as first medicine in its class on its diabetes protocol for appropriate patients'. A direct link between the company's support and the potential use of Avandamet was thus implied. Paragraph 3.1 of the contract between the primary healthcare service company and GlaxoSmithKline stated 'This Project is sponsored by GlaxoSmithKline. As a consequence of the Group's decision to place GlaxoSmithKline's product on the Group's Protocol in accordance with paragraph 2.6 above, GlaxoSmithKline has agreed to provide funding for this service: provision of such funding is not conditional on the prescription of that product'. In the Appeal Board's view it was immaterial that the protocol did not refer to Avandamet as a named medicine; that it would do so was the basis upon which the contract was signed.

At the appeal GlaxoSmithKline acknowledged that the wording used in paragraph 3.1 of the contract was not the best it could be.

The Appeal Board noted GlaxoSmithKline's submission that the treatment protocol had existed before its involvement with the Diabetes HCP and that the company had not influenced it in any way; it had not changed as a result of the contract between the primary healthcare service company and GlaxoSmithKline. This was not the impression given by the voicemail and the contract.

The Appeal Board noted the content of the protocol which stated that when a glitazone was to be added to metformin, rosiglitazone was second line. Combination tablets of glitazone and metformin were only to be used if there were compliance problems. It also noted GlaxoSmithKline's submission that the positioning described was consistent with NICE guidance.

The Appeal Board further noted GlaxoSmithKline's submission that the naming of Avandamet in the contract was for the purposes of transparency. The Appeal Board considered that in this regard it was not inappropriate *per se* to refer to products but the manner in which they were referred to and the context was important. Encouraging appropriate use of a product in line with national and local guidelines was different to a contractual arrangement that a protocol be changed. The Appeal Board considered that in the voicemail and in the contract there was a very definite, unequivocal link made between the provision of funding and the inclusion of Avandamet, for use as appropriate, on the protocol.

The Appeal Board noted that in response to questioning at the appeal GlaxoSmithKline stated that the company's sponsorship of the Diabetes HCP (£29,250) had part-funded the provision of a diabetes nurse. The Appeal Board further noted that the Diabetes HCP was the mechanism by which the primary healthcare service company delivered its diabetes service. The relationship between the primary healthcare service company and GlaxoSmithKline was an evolving relationship. GlaxoSmithKline provided the primary healthcare service company with, *inter alia*, education, training and business planning. The two organisations worked together on, *inter alia*, project management, data analysis and communications.

The Appeal Board considered that the Diabetes HCP had merit. However the way it had been described in the voicemail and the manner in which Avandamet had been referred to in the contract was evidence that the provision of funding had been linked to the product. The Appeal Board upheld the Panel's ruling of a breach of Clause 18.4. The appeal on this point was thus unsuccessful.

Although noting its ruling above the Appeal Board nonetheless did not consider that taking all the circumstances into account that GlaxoSmithKline had failed to maintain high standards. No breach of Clause 9.1 was ruled. The appeal on this point was thus successful.

Complaint received	**20 February 2008**
Case completed	**1 July 2008**