CASE AUTH/2322/5/10

VOLUNTARY ADMISSION BY ASTRAZENECA

Conduct of representative

AstraZeneca voluntarily admitted breaches of the Code in that a contract representative arranged for a practice nurse at one surgery to undertake a clinical review of chronic obstructive pulmonary disease (COPD) patients at another surgery. The arrangements were not reviewed or approved by AstraZeneca and nor were any documents or records generated in relation to the service.

The Authority's Constitution and Procedure provided that a voluntary admission should be treated as a complaint if it related to potentially serious breaches of the Code or if the company failed to address the matter. That a representative arranged for a clinical review of patients without the company's knowledge was a potentially serious matter and the admission was thus treated as a complaint.

AstraZeneca stated that although the representative had left the employment of the contract sales organisation before the concern about his conduct was raised (and therefore no longer worked for or on behalf of AstraZeneca), it had established the following:

In November 2009 the representative agreed with a practice nurse that that nurse would undertake a clinical review of COPD patients at another local practice and train the resident practice nurse there on findings from the review.

The representative entered into this agreement under his own initiative. He had not been instructed, required, briefed or trained by anyone from AstraZeneca or any other organisation to undertake such an activity.

The representative misleadingly submitted this activity for approval by his AstraZeneca manager, describing it as a speaker's agreement with the nurse. The approval request did not refer to the delivery of clinical patient reviews. The manager challenged the proposed payment (£300) for speaking but the representative implied that that represented fair market value for the nurse in question. Clinical review services were not mentioned by the representative to the manager. The manager approved the request for what he believed was a straightforward educational speaking engagement.

No written agreements existed of any kind between any of the interested parties. Nor were any other documents generated in relation to the service.

The nurse at the practice where the service was to be delivered discussed the service with the GP lead at that practice. The GP believed that he saw a service protocol and subsequently gave verbal approval to his practice nurse for the service to proceed. AstraZeneca did not have a copy of this protocol.

The nurse who delivered the service reviewed 30-40 patients according to standards of good clinical practice. The nurse did not declare to any of the patients that she was being sponsored by AstraZeneca (and nor did the representative request that the nurse make such a declaration).

The verbal agreement between the nurse and representative specified a payment of £20/hour, resulting in a total of approximately £300 for all the hours of service delivered by the nurse. However, AstraZeneca had not paid these monies and would not.

The representative had been comprehensively trained on the requirements of the Code and relevant AstraZeneca policies. He had also passed the ABPI representatives' examination. Despite this training, he initiated unapproved activities without following appropriate AstraZeneca processes and misled AstraZeneca about the nature of those activities. The representative had not maintained a high standard of ethical conduct in the discharge of his duties.

AstraZeneca provided details of some of the corrective actions it had taken both in-house and with the practice where the clinical review was performed.

The detailed response from AstraZeneca is given below.

The Panel noted that without AstraZeneca's knowledge, the representative in question had arranged for a nurse from one general practice to review COPD patients in another practice and train the nurse at the second practice on the findings from the review. The representative had offered to pay the nurse and, in order to get the expenditure approved, had told his manager that the nurse would be 'doing a COPD meeting and discussing how Symbicort fits in for [AstraZeneca]. She will also spend a little time doing some case studies'. When the manager queried the agreed fee of £300 the representative stated that the nurse was very influential within respiratory circles and had spoken for AstraZeneca before. The representative further stated that the nurse knew that £300 did not reflect the usual honoraria for speaking. The manager then agreed to the payment. The fee had not been paid.

The Panel considered that the representative's conduct was wholly unacceptable and, although he had acted on his own initiative and against company policy, AstraZeneca was nonetheless responsible for his actions. The Panel was extremely concerned that there was no way of knowing if the nurse, who had reviewed the COPD patients, had the necessary expertise to perform the task for which the representative had offered to pay. The Panel queried whether, as a result, patients had been put at risk. It appeared that the nurse had undertaken a therapy review service and the involvement of AstraZeneca had not been made clear to patients. No documentation or records of the service had been kept if such materials had been produced.

The Panel considered that the provision of an unapproved, ad hoc medical service by a representative whose role was to promote medicines was unacceptable. A breach of the Code was ruled. The Panel noted that it was clear that materials had either not been produced or not been kept. The GP referred to a protocol which AstraZeneca had not been given. The Panel considered that as no materials had been supplied and given the circumstances it decided that there was not sufficient information to rule a breach with regard to the need for certification and thus no breach of the Code in that regard was ruled.

The Panel did not consider that the representative had maintained a high standard of ethical conduct. A breach of the Code was ruled.

The Panel noted AstraZeneca had known nothing about the clinical review until after the event, the Panel nonetheless considered that high standards had not been maintained. The Panel noted that the requested fee of £300 exceeded AstraZeneca's stated company policy with regard to the recommended payment for a nurse speaker which, for a presentation, typically 1-1½ hours including some preparation, was £150-£250. In the Panel's view a request for a higher than normal honorarium to a nurse not known to the representative's manager as being a local opinion leader should have been more closely scrutinised and should have required the provision of some supporting documentation from the representative. In that regard the Panel requested that AstraZeneca be reminded of the requirements of the Code with regard to the use of consultants. As it was, the expenditure was agreed over the course of two days and four very short emails between the manager and the representative. There appeared to be a lack of management control. High standards had not been maintained. A breach of the Code was ruled which was appealed.

The Panel considered that the representative's conduct, and the lack of control within AstraZeneca which allowed the clinical review to take place, brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled which was appealed.

The Appeal Board noted that the representative at issue had only worked for AstraZeneca for a few months and had left the company in January 2010 following concerns about poor performance including administration issues. AstraZeneca's representatives at the appeal explained that the company first knew about the clinical review in February when the nurse who had carried out the work, and who could no longer contact the representative, contacted the company direct to request payment. The representative's manager had immediately raised the matter and this had prompted an internal investigation which subsequently led to AstraZeneca's voluntary admission.

The Appeal Board noted that AstraZeneca had policies and procedures in place to ensure compliance with the Code and, assuming compliance with those policies and procedures, the representative's manager had, with little resistance, taken the representative's account of the planned speaker meeting at face value. AstraZeneca's representatives at the appeal stated that the manager had no reason to suspect malintent or subterfuge. Nonetheless, the Appeal Board considered that more diligence should have been exercised with regard to the approval of a payment to a speaker that was outwith the company's stated policy.

The Appeal Board considered that the representative's deception of his manager was wholly unacceptable. Although the representative had acted alone in this regard, and contrary to company policy and training, AstraZeneca was nonetheless responsible for his actions. In the Appeal Board's view the manager should have shown much greater scrutiny. High standards had not been maintained. The Appeal Board upheld the Panel's ruling of a breach of the Code. The appeal on this point was thus unsuccessful.
The Appeal Board noted its comments and ruling above and considered that, on balance and given the particular facts of this case, AstraZeneca had not brought discredit upon or reduced confidence in the pharmaceutical industry. The Appeal Board ruled no breach of Clause 2. The appeal on this point was thus successful.

AstraZeneca UK Limited voluntarily admitted breaches of the Code in that a contract representative arranged for a practice nurse at one surgery to undertake a clinical review of chronic obstructive pulmonary disease (COPD) patients at another surgery. The arrangements were not reviewed or approved by AstraZeneca and nor were any documents or records generated in relation to the service.

Paragraph 5.4 of the Constitution and Procedure provided that a voluntary admission should be treated as a complaint if it related to potentially serious breaches of the Code or if the company failed to address the matter. That a representative arranged for a clinical review of patients without the

company's knowledge was a potentially serious matter and the admission was thus treated as a complaint.

COMPLAINT

AstraZeneca stated that the representative in question was employed by a contract sales organisation. Although the representative had left the employment of the contract sales organisation before the concern about his conduct was raised (and therefore no longer worked for or on behalf of AstraZeneca), AstraZeneca had established the following:

In November 2009 the representative, working for AstraZeneca, verbally agreed with a practice nurse that that nurse would undertake a clinical review of COPD patients at another local practice and train the resident practice nurse there on findings from the review.

- The representative entered into this agreement under his own initiative. He had not been instructed, required, briefed or trained by anyone from AstraZeneca or any other organisation to undertake such an activity.

- The representative misleadingly submitted this activity for approval by his AstraZeneca manager, describing it as an agreement with the nurse to deliver an educational speaking engagement. The approval request did not refer to the delivery of clinical patient reviews. The manager challenged the proposed payment (£300) for a speaking engagement but the representative implied that that represented fair market value for the nurse in question. Clinical review services were not mentioned by the representative to the manager. The manager approved the request for what he believed was a straightforward educational speaking engagement.

- Neither the representative nor any other party created a written agreement of any kind. No written agreements existed between AstraZeneca and the nurse or between AstraZeneca and the practice where the service was to be delivered.

- No written material relating to the service was generated by the representative and nor was such material certified. Therefore, AstraZeneca believed there had been a breach of Clauses 14.1 and 18.4 of the Code.

- No documents in relation to this service were generated or kept on record by the company. Therefore, AstraZeneca believed there had been a breach of Clause 18.5.

- The representative told the practice where the service was to be delivered that such a service was being arranged and again, verbally agreed with the nurse at that practice for its delivery.

- The nurse at the practice where the service was to be delivered discussed the service with the GP lead at that practice. The GP believed that he saw a protocol for the service and subsequently gave verbal approval to his practice nurse for the service to proceed. AstraZeneca had not been able to secure a copy of this protocol.

- The nurse who delivered the service reviewed approximately 30 to 40 patients according to standards of good clinical practice. The nurse did not declare to any of the patients that she was being sponsored by AstraZeneca to undertake the review (and nor did the representative request of the nurse that she make such a declaration). Therefore, AstraZeneca believed there had been a breach of Clause 9.10.

- The verbal agreement between the nurse and representative specified a payment of £20/hour, resulting in a total of approximately £300 for all the hours of service delivered by the nurse. However, AstraZeneca had not paid these monies and would not.

The representative had been comprehensively trained by AstraZeneca (and the contract sales organisation) on the requirements of the Code, including those related to medical and educational goods and services, as well as the AstraZeneca External Meetings Policy. He had also passed the ABPI examination for representatives. Despite this training, he initiated unapproved activities without following appropriate AstraZeneca processes and misled AstraZeneca about the nature of those activities. The representative had not maintained a high standard of ethical conduct in the discharge of his duties. Therefore, AstraZeneca believed there had been a breach of Clause 15.2.

AstraZeneca stated that in terms of corrective action, it had contacted the practice where the service was undertaken and fully disclosed this unapproved service to the GP lead there. In particular, the company disclosed the fact that the nurse had not declared AstraZeneca sponsorship to the patients reviewed and nor had AstraZeneca put in place written or verbal requirements for this to occur. AstraZeneca explicitly asked the GP whether further corrective actions were required and was informed not.

AstraZeneca was thoroughly reviewing the representative recruitment and training processes used by the contract sales organisation in question in order to ensure that they met the standards required by AstraZeneca (although AstraZeneca did not rely solely on those processes since representatives supplied by the contract sales organisation were required to undergo the full AstraZeneca Initial Training Course (ITC) and validation).

AstraZeneca stated that it would train all sales personnel, including managers, on the final learnings from this case once it was completed.

Finally, in terms of corrective action AstraZeneca noted that it had submitted this voluntary admission.

AstraZeneca stated that it took compliance with the Code extremely seriously and believed that this was an isolated incident in which a trained contract sales representative initiated an unrequested and unapproved activity and misled his AstraZeneca manager with regard to the nature of that activity. The representative left the employment of the contract sales organisation before the concern was raised and had not worked for or on behalf of AstraZeneca since.

In addition to those clauses cited by AstraZeneca, when writing to inform it that the voluntary admission would be taken up as a complaint, the Authority asked it to comment in relation to the requirements of Clauses 2 and 9.1.

RESPONSE

AstraZeneca explained that the representative was employed by the contract sales organisation as a full-time AstraZeneca representative between April 2009 and January 2010. The representative's services were supplied under the terms of a detailed contract between the companies which included requirements for contract sales organisation to comply with the Code.

As part of his initial training course, the representative received the following comprehensive training from the contract sales organisation and AstraZeneca:

- As part of its training program for representatives, the contract sales organisation trained the representative on the Code in April 2009, and this included specific instruction on Clause 18. The representative passed a written test of his knowledge of the Code at the end of this training.

- This was reinforced by the training in May 2009 by AstraZeneca on the Code, as part of its comprehensive training program for representatives; this also included specific instruction on the requirements of Clause 18.

- The representative was also required to read, acknowledge his compliance with, and pass an examination on his understanding of the AstraZeneca 'UK Pharma Code'. This was a comprehensive AstraZeneca internal policy based on the Code. It covered the AstraZeneca requirements for promotional and non-promotional activities undertaken by representatives and other company personnel, including the requirements for medical and educational goods and services. The representative passed the examination for this policy and acknowledged his compliance with it in May 2009. This policy explicitly stipulated that 'Materials relating to the provision of medical and educational goods and services … must be examined by the local Nominated Signatories and certified as acceptable under all applicable internal and external codes, laws and regulations'. The representative did not submit nor receive any such approval from any AstraZeneca or contract sales organisation personnel.

- The representative was also required to read and acknowledge his compliance with the AstraZeneca Global Code of Conduct, and he did so in May 2009. This was an internal code which required all employees to maintain high standards of ethical conduct in all their activities.

- The representative had passed the ABPI examination for representatives.

Despite all the above training, the representative initiated activities that had not been reviewed or approved through appropriate AstraZeneca processes and misled his AstraZeneca manager about the nature of those activities. As required by company guidance regarding payment of speakers' fees to health professionals, the representative requested approval from his manager for planned costs of £350 (comprised of a £300 fee to the nurse and £50 budgeted for subsistence and expenses) using the AstraZeneca electronic territory management system. However, the request was presented as approval of a proposed cost for the nurse to deliver an educational meeting ('speaker meeting'). There was no indication in the approval request, either explicit or implicit, that the proposal included delivery of patient clinical review services.

In the course of email correspondence, the manager queried the justification for the level of the proposed honorarium (even though it was potentially within AstraZeneca guidance regarding payment of speakers' fees). The representative responded with a justification based on the fair market value of the nurse. The representative, again, did not use this opportunity to declare the true nature of the proposed activity to his manager and continued to present the activity as a speaker meeting. The manager then approved this proposed fee, in the reasonable belief that it was for an educational speaker meeting. AstraZeneca noted that once the circumstances of this activity were investigated and established, the company did not, and would not, pay the fee.

AstraZeneca stated that the representative appeared to have willfully misled the manager and such isolated, deliberate acts could not, in every instance, be reasonably prevented by policies, processes or managerial oversight even where these were robust.

AstraZeneca encouraged and set out clear internal processes for all employees to raise concerns relating to compliance. In this case, concerns were raised by the representative's manager when he was contacted by the nurse requesting payment for

this clinical service (after the representative had left employment with the contract sales organisation and AstraZeneca).

In response to the concerns raised, a thorough investigation was undertaken to establish the facts and AstraZeneca noted the corrective actions it had taken as detailed above.

AstraZeneca considered that the representative was comprehensively trained on the Code as part of established and robust company training programs and that reasonable control was exercised over their activity, as set out above.

When a potential compliance concern was raised internally, AstraZeneca immediately undertook a thorough investigation and took internal and external corrective actions as set out above because it took compliance with the Code extremely seriously. Therefore, AstraZeneca denied a breach of Clause 9.1.

The representative appeared to have acted in a willfully misleading manner and in contravention of his training. AstraZeneca believed this was an isolated and unforeseeable individual act which was identified and acted upon internally. Therefore, AstraZeneca did not consider there had been a breach of Clause 2.

PANEL RULING

The Panel noted that without AstraZeneca's knowledge, the representative in question had arranged for a nurse from one general practice to review COPD patients in another practice and train the nurse at the second practice on the findings from the review. The representative had offered to pay the nurse and, in order to get the expenditure approved, had told his manager that the nurse would be 'doing a COPD meeting and discussing how Symbicort fits in for [AstraZeneca]. She will also spend a little time doing some case studies'. When the manager queried the agreed fee of £300 the representative stated that the nurse was very influential within respiratory circles and had spoken for AstraZeneca before. The representative further stated that the nurse knew that £300 did not reflect the usual honoraria for speaking. The manager then agreed to the payment. The fee had not been paid.

The Panel considered that the representative's conduct was wholly unacceptable and, although he had acted on his own initiative and against company policy, AstraZeneca was nonetheless responsible for his actions. The Panel was extremely concerned that there was no way of knowing if the nurse, who had reviewed the COPD patients, had the necessary expertise to perform the task for which the representative had offered to pay. The Panel queried whether, as a result, patients had been put at risk. It appeared that the nurse had undertaken a therapy review service and the involvement of AstraZeneca had not been made clear to patients. No documentation or records of the service had been kept if such materials had been produced.

The Panel considered that the provision of an unapproved, ad hoc medical service by a representative whose role was to promote medicines was unacceptable. A breach of Clause 18.4 was ruled. The Panel noted that AstraZeneca had acknowledged a breach of Clause 14.1 as materials had not been certified. Clause 14.1 related to promotional material and clearly a medical or educational good or service should not be promotional. Clause 14.3 required certification of materials for patients or health professionals relating to the provision of medical and educational goods and services including relevant internal company instructions. AstraZeneca had not been asked to respond in relation to the requirements of Clause 14.3. It was clear that materials had either not been produced or not been kept. The GP referred to a protocol which AstraZeneca had not been given. The Panel considered that as no materials had been supplied and given the circumstances it decided that there was not sufficient information to rule a breach of Clause 14.1 and thus ruled no breach.

The Panel noted its ruling of a breach of Clause 18.4, it thus considered that the matter was not covered by Clause 18.5 which referred to activities not otherwise covered by the Code. No breach of Clause 18.5 was ruled.

The Panel did not consider that the representative had maintained a high standard of ethical conduct. A breach of Clause 15.2 was ruled.

The Panel noted that AstraZeneca had acknowledged the breaches of the Code as detailed above. The company had, in addition, been asked to consider the requirements of Clauses 9.1 and 2 of the Code. Although noting that AstraZeneca had known nothing about the clinical review until after the event, the Panel nonetheless considered that high standards had not been maintained. The Panel noted that the requested fee of £300 exceeded the recommended payment for a nurse speaker as stated in AstraZeneca's External Meetings Policy document. According to the company's stated policy, nurse speakers (for a presentation, typically 1-11/2 hours including some preparation) were to be paid £150-£250. In the Panel's view a request for a higher than normal honorarium to a nurse not known to the representative's manager as being a local opinion leader should have been more closely scrutinised and should have required the provision of some supporting documentation from the representative. In that regard the Panel requested that AstraZeneca be reminded of the requirements of Clause 20. As it was, the expenditure was agreed over the course of two days and four very short emails between the manager and the representative. There appeared to be a lack of management control. High standards had not been maintained. A breach of Clause 9.1 was ruled. This ruling was appealed.

The Panel considered that the representative's conduct, and the lack of control within AstraZeneca which allowed the clinical review to take place, brought discredit upon and reduced confidence in the pharmaceutical industry. A breach of Clause 2 was ruled. This ruling was appealed.

APPEAL BY ASTRAZENECA

AstraZeneca reiterated that it took adherence with the Code extremely seriously; it had created a culture that encouraged employees to internally raise compliance concerns secure in the knowledge that such concerns would be investigated and addressed appropriately. Consistent with that culture, this compliance issue was internally raised in response to which AstraZeneca conducted a thorough investigation and submitted a voluntary admission.

AstraZeneca submitted that with regard to the ruling of a breach of Clause 9.1, the Panel noted that AstraZeneca had known nothing about the clinical review until after the event but it nonetheless considered that high standards had not been maintained. This conclusion was reached on the basis that the proposed fee to the nurse of £300 exceeded the recommended guidance for a nurse speaker in the AstraZeneca External Meetings Policy. It was the Panel's view that such a proposal should have been more closely scrutinized and that there appeared to be a lack of management control. The Panel stated that as it was, the expenditure was agreed over the course of two days and four very short emails between the manager and the representative. In responding to these points, AstraZeneca reiterated the actions that the manager took to exercise control over the proposed activity.

AstraZeneca noted that in November 2009, the representative submitted the proposed educational meeting for approval by his manager, entering the details into AstraZeneca electronic territory management system. A printout of those details, previously provided, clearly identified the proposed activity as a 'Speaker Meeting' to take place in November 2009.

AstraZeneca provided a 'screenshot' of the information the manager would have seen on his computer screen when viewing the details of the proposed activity in the electronic territory management system. This clearly showed that under the heading 'Event Type', the representative had specified 'Speaker Meeting'. Under the heading 'Objective', he had stated 'Further account objectives' and under 'Recruitment Criteria' (ie nature of delegates), he had stated 'Drs and nurses'. He had also indicated that the proposed number of delegates was 5 and that the average cost per head would be £70. The field requiring approval by the manager was headed 'Meeting Approved by' and the optional field for 'Meeting Notes' was left blank. Therefore, it appeared to the manager that this proposed activity, for their approval, was purely a speaker meeting.

Despite the apparently straightforward nature of the representative's proposal the manager challenged the request for approval, as shown in the email exchange previously provided. The manager challenged the level of expenditure by asking 'Is [nurse] a very well respected KOL [key opinion leader] as this seems a large honoraria for a first meeting or has she spoken for us before?' In response to this challenge, the representative stated '[Nurse] is very influential within respiratory circles and she has spoken for us in the past. This is higher than the usual fee as a one off as she is doing the meeting then spending some time on top doing some COPD case studies to really bring the meeting content to life for us'. With this information before them, AstraZeneca did not believe that it was unreasonable for the manager to consider that he was approving fees for a speaker with a high market value and that the speaker would need to spend a significant amount of time (above and beyond that needed for an average speaker meeting) preparing case studies specifically for this meeting. Based on such consideration, AstraZeneca did not believe it was unreasonable for the manager to approve a fee that was a little above the guidance in the AstraZeneca External Meetings Policy (ie they approved £300 rather than £250), as compensation for the significant amount of extra time that would have been reasonably expected to be required to prepare new case studies specifically for this meeting. AstraZeneca therefore submitted that the proposed fee was not inconsistent with its External Meetings Policy.

AstraZeneca submitted that the manager had no reason to consider that the information supplied by the representative wholly misrepresented the nature of the activity type. Therefore, and for the reasons described above, AstraZeneca submitted that the manager acted in a reasonable and proportionate manner; the company did not agree that there was a lack of management control and nor therefore, that there had been a breach of Clause 9.1.

AstraZeneca noted that with regard to the ruling of a breach of Clause 2, the Panel considered '… that the representative's conduct, and the lack of control within AstraZeneca which allowed the clinical review to take place, brought discredit upon and reduced confidence in the pharmaceutical industry'.

AstraZeneca agreed that the representative in this instance did not maintain a high standard of ethical conduct and did not comply with all relevant requirements of the Code. This was despite the extensive training he received and acknowledged on the Code and company policy from both AstraZeneca and the contract sales organization. Accordingly, AstraZeneca had accepted a ruling of a breach of Clause 15.2. However, for the detailed reasons set out below, AstraZeneca did not agree that there had been a lack of control.

AstraZeneca submitted that it had robust contracts

and detailed policies in place that governed the actions of representatives and the processes and systems to ensure that these were implemented. The company had a dedicated Learning & Development department that created and delivered extensive mandatory training to all new representatives (including contract sales representatives) on the technical aspects of products they were required to promote, how they were to promote them and the compliance requirements related to their role, as well as the requirements of the Code (including the requirements of Clause 18). The representative in question underwent this training in April 2009.

All company personnel and contracted sales personnel were required to demonstrate a thorough understanding of the 'AstraZeneca UK Pharma Code' and to pass a test assessing their knowledge and understanding of it. They were then required to record their acknowledgement that they understood, and would comply with this code. This code was an extensive document based on the ABPI Code and provided a great deal of specific guidance on the activities of personnel including representatives. It covered the AstraZeneca requirements for promotional and non-promotional activities undertaken by representatives and other company personnel, including the requirements for medical and educational goods and services. The representative passed the examination for this policy and acknowledged his compliance with it in May 2009. The policy explicitly stipulated that 'Materials relating to the provision of medical and educational goods and services…must be examined by the local Nominated Signatories and certified as acceptable under all applicable internal and external codes, laws and regulations'. The representative in this case did not submit nor receive any such approval from anyone in AstraZeneca or the contract sales organisation.

All AstraZeneca personnel and contract sales personnel were required to annually read and acknowledge their understanding and compliance with the 'AstraZeneca Global Code of Conduct'. This overarching AstraZeneca code required all employees and third party service providers (including contracted sales personnel) to act with integrity and maintain a high standard of ethical conduct at all times. The representative in this case acknowledged his compliance with this code in May 2009.

AstraZeneca had robust contractual provisions in place with all of its contract sales organizations including the one that had employed the representative in question. The contract sales organisation and its employees were obliged under the terms of the contract to carry out any and all services on behalf of AstraZeneca in compliance with the Code, and only through sales representatives who were appropriately trained, had passed the validation and had the relevant skills, knowledge, qualification and experience to undertake their tasks in a professional and competent manner. Furthermore, AstraZeneca's contracts obligated the contract sales organisation to promptly inform AstraZeneca of any circumstances it became aware of (for whatever reason) regarding any of its employees that made that person unsuitable to provide services on behalf of AstraZeneca. The representative in this case had passed the ABPI examination for representatives in 2006, had undergone initial training on the Code by the contract sales organisation in April 2009 (including the requirements of Clause 18) and had passed a written test demonstrating his knowledge of the Code at the end of this training. This training was in addition to the training administered separately by AstraZeneca on the Code and the requirements of Clause 18, referred to above.

AstraZeneca submitted that all of its representatives were required to attend a quarterly local training meeting on the Code, delivered by specially trained members of their regional sales management during which recent PMCPA cases relevant to the field and other topical matters related to the Code were presented and discussed. The representative in this case attended such a meeting during his seven months of active service with AstraZeneca.

All representatives were trained in detail on the AstraZeneca electronic territory management system which was a comprehensive resource for recording calls on health practitioners and for planning, recording and approving proposed educational or promotional meetings. There was no process available within that system for the approval of patient review services. The training representatives received on the approval of meetings using the system did not refer to patient review services in any way, nor could there be any misunderstanding that the meetings approval process could be used for the approval of patient review services. The representative in this case underwent detailed training on the system in April 2009.

AstraZeneca submitted that it strongly encouraged its employees and third party service providers to raise any compliance concerns they had and provided a process and independent resource for doing this. Employees might raise issues, through a number of routes, including an independently administered telephone line and web-site. This was a key control mechanism, above and beyond that required by the Code.

AstraZeneca re-emphasised that this compliance issue was initially brought to its attention as a result of an internally raised concern. When contacted by AstraZeneca, the GP in the practice where the patient reviews took place did not raise a complaint or request any further corrective actions. The fact that the compliance issue was raised internally was in keeping with the culture at AstraZeneca that encouraged employees to raise such concerns in the knowledge that they would be investigated and addressed appropriately. AstraZeneca treated this case with the seriousness it merited when it was

raised and conducted a thorough investigation and corrective actions. In that regard AstraZeneca noted that it had submitted a voluntary admission to the PMCPA. The company had also contacted the practice where this service was undertaken and fully disclosed to the GP lead there that the patient review service had not been arranged according to appropriate AstraZeneca processes and that written agreements had not been put in place by AstraZeneca with the practice. AstraZeneca had disclosed the fact that the nurse had not declared AstraZeneca support to the patients reviewed. AstraZeneca explicitly asked the GP whether he required further actions of a corrective nature of any kind and was informed that he did not. In addition AstraZeneca had undertaken a thorough review of the representative training processes used by the contract sales organisation in question in order to ensure it met the standards required by AstraZeneca. AstraZeneca would train all sales personnel, including managers, on the final learnings from this case once it was completed.

AstraZeneca fully understood that all companies had a responsibility to have in place adequate procedures designed to prevent persons from undertaking activities in breach of the Code. AstraZeneca submitted that it had in place such procedures and controls and that these were over and above the minimum standard required and had applied them in this case. However, despite the robust contract, systems/processes and training, the representative appeared to have acted on his own volition to proactively circumvent these controls and procedures without AstraZeneca's instruction, knowledge or approval. AstraZeneca did not agree that such actions or omissions of the representative in this case indicated a lack of adequate control.

AstraZeneca re-emphasized that it took the positive decision to submit a voluntary admission - such openness and transparency would ultimately enhance the reputation of the industry and bring credit upon it rather than the converse.

AstraZeneca submitted that there had not been a lack of control nor had this matter brought discredit to or reduced confidence in the industry. Therefore, AstraZeneca denied a breach of Clause 2.

In summary, AstraZeneca submitted that it had in place the reasonable controls and more, expected of a pharmaceutical company and applied those controls in this case as set out above and that the circumstances of this matter were not such as to warrant a ruling of breaches of Clauses 2 and 9.1.

APPEAL BOARD RULING

The Appeal Board noted that the representative at issue had only worked for AstraZeneca for a few months. The representative had left the company in January 2010 following concerns about poor performance including administration issues. AstraZeneca's representatives at the appeal explained that the company first knew about the clinical review in February when the nurse who had carried out the work, and who could no longer contact the representative, contacted the company direct to request payment. The representative's manager had immediately raised the matter and this had prompted an internal investigation which subsequently led to AstraZeneca's voluntary admission.

The Appeal Board noted that AstraZeneca had policies and procedures in place to ensure compliance with the Code and, assuming compliance with those policies and procedures, the representative's manager had, with little resistance, taken the representative's account of the planned speaker meeting at face value. AstraZeneca's representatives at the appeal stated that the manager had no reason to suspect malintent or subterfuge. Nonetheless, the Appeal Board considered that more diligence should have been exercised with regard to the approval of a payment to a speaker that was outwith the company's stated policy.

The Appeal Board considered that the representative's deception of his manager was wholly unacceptable. Although the representative had acted alone in this regard, and contrary to company policy and training, AstraZeneca was nonetheless responsible for the representative's actions. In the Appeal Board's view the manager should have shown much greater scrutiny. High standards had not been maintained. The Appeal Board upheld the Panel's ruling of a breach of Clause 9.1. The appeal on this point was thus unsuccessful.

The Appeal Board noted its comments and ruling above and considered that, on balance and given the particular facts of this case, AstraZeneca had not brought discredit upon or reduced confidence in the pharmaceutical industry. The Appeal Board ruled no breach of Clause 2. The appeal on this point was thus successful.

Complaint received **25 May 2010**

Case completed **6 August 2010**