HOSPITAL DOCTOR v ASTRAZENECA

Representatives training event

A hospital doctor complained about an invitation to participate in a day-long workshop in June 2011. The invitation had been sent by a market research agency on behalf of AstraZeneca.

The invitation, headed 'Training day research invitation', stated that the market research agency was 'conducting a study with specialists and medical reps. The research involves a day long workshop which includes running mock consultations with reps as well as doing some group and individual exercises'. The aim was to improve representatives' performance and gain feedback on what 'would make rep visitations more useful …'. Participating health professionals would receive £600 for taking part. The invitation stated that 'The research is also purely an exercise so in no way will any element of day be promotional'.

The complainant stated that the invitation was clearly not targeted to her for her specific expertise since she was not an expert in training sales representatives.

The complainant replied to the invitation stating that these events were 'rather sophisticated attempts to get doctors to listen to the same marketing information repeatedly, getting round the problem of paying doctors to become brainwashed, by calling it rep training'. The complainant stated that this was ethically dubious.

The detailed response from AstraZeneca is given below.

The Panel noted that the complainant raised concerns about the invitation. The complainant had not attended the training. The Panel considered that in order to determine whether the invitation was appropriate it had to determine first whether the training was appropriate. The Panel noted that the complainant was concerned that the invitation was not targeted to her for her specific expertise as she was not an expert in training sales representatives. The complainant had been asked to recruit colleagues to attend. In replying to the invitation the complainant stated that the events were sophisticated attempts to get doctors to listen to the same marketing information repeatedly and 'getting round the problem by paying doctors to become brainwashed by calling it rep training'.

The Panel noted that the assessment had been organized by a training service provider on behalf of AstraZeneca. The invitation at issue had been sent by an agency on behalf of the training service provider.

Neither AstraZeneca nor the training service provider had seen the invitation. This was of serious concern to the Panel and in its view indicated a lack of control. The Panel noted AstraZeneca's comments on its relationship with the training service provider. AstraZeneca was responsible under the Code for the acts and/or omissions of the training service provider, and the two other agencies. The Panel noted that there was no AstraZeneca document specifically briefing the training service provider in relation to the details of the training events. An AstraZeneca document setting out the ambition for the project in terms of upskilling the representatives shared with the training service provider was provided.

The invitation stated that the author was 'conducting a study with specialists and medical reps' and referred to 'research'. The Panel considered that the invitation to the complainant was not sufficiently clear that it was not a market research event but related to an assessment of the performance of the representatives. The invitation stated that it was 'a day long workshop, which includes running mock consultations with reps as well as doing some group and individual exercises'. In the Panel's view the invitation implied that the mock consultations were only part of the agenda as there would be group and individual exercises. The invitation did not state that it was a pharmaceutical company event. There was no indication of the nature of the client.

The Panel considered that the invitation to the complainant was due to her professional experience and not in relating to training sales representatives. In the Panel's view this was not unacceptable.

The Panel then turned its attention to the arrangements for the meeting in question.

The Panel noted that one of the slides describing the Capability Development Centre (CDC) referred to local events and local customers. The Panel accepted that the local conditions could be relevant to some aspects of representatives' calls and performance. The Panel noted that in 2010 the CDC training event had been run nationally, rather than on a regional basis. The Panel considered that it would be possible to adapt a national format whilst ensuring that local differences, such as differences between the devolved nations, were met. The Panel did not accept the company's submission on this point.

The Panel was very concerned that the local nature of the events meant that it was highly likely that some of the health professionals participating in the training were those upon whom the same representatives would be calling on, or had previously called on, in a professional capacity. In the Panel's view it would have been preferable if the arrangements were such that no representative was assessed by a health professional or payer upon whom they were expected to call. AstraZeneca had not issued any guidance for representatives in this regard. Robust safeguards should be in place to ensure a clear separation between the training and subsequent contact given the local nature of the activity.

The Panel noted that each medical representative was to be assessed three times and was given 15 minutes for the assessed call. The Panel queried whether this was in line with what happened in the field but noted the company submission that the duration and number was not out of line with other companies' training arrangements, was much more statistically robust and gave a better indication of the true capability of the representative. The Panel had similar concerns with the time allocated to the integrated healthcare specialists assessed calls (30 minutes).

Clearly it was important to train representatives and to assess that training but the Panel had some concerns about the scale of the activity. The Panel queried whether it was necessary for every representative to be assessed for 3 calls, particularly in relation to those calling upon GPs. In this regard the Panel noted that in total 304 representatives participated in 11 events with 910 assessed calls involving 206 health professionals. The Panel queried whether the number of health professionals/payers retained was consistent with the Code which required that the number of consultants was not greater than the number reasonably necessary to achieve the identified need.

The Panel had some concerns about frequency of the events and the genuine need for further assessment as it appeared that nine representatives had already been assessed on the same parameters twice since October 2010.

The Panel queried the validity of AstraZeneca representatives undertaking repeat assessed calls with the same health professional/payer. The Panel was also concerned that the AstraZeneca sales team referred the names of health professionals to their manager for possible invitation to the event.

The use of a health professional on the 'hot desk' was of concern. Attendance at the hot desk was not mandatory. Representatives were encouraged to visit the hot desk. The Panel understood the difficulty in recruiting health professionals/payers and understood the need to ensure that the event ran if some health professionals/payers did not turn up on the day. However, it seemed that the roles were different and it was difficult to justify the payments being the same.

The Panel noted that the health professional/payer completed 6 questions following the interview. The questions did not mention the product and focused mostly on the health professional/payer's professional needs. There was no mention of marketing messages. They were asked whether they would act differently as a result of this conversation.

The observer (either a training service provider member of staff, an external contractor or an AstraZeneca sales manager) completed one form for health professional calls and another for payer calls. The observer health professional form was divided into sections 'Open and identify/clarity needs', 'Engage customer in compelling proposition - skills', 'Engage customer in compelling proposition - knowledge', 'Close and agree joint and future action', 'Overall Impact' and 'Emotional Intelligence'. Comments on a key strength and a key development area and overall comments were also required.

The observer payer form was different in that it included a section at the end for the observer to interview the payer to identify a key strength and a key development area. In addition the payer was asked about how compelled they were to see the individual again and whether they would change their behavior as a result of seeing the individual.

The Panel noted that payers were offered a higher consultant fee at £700 than either the GP (£500) or the specialist (£600). These rates did not reflect the AstraZeneca maximum hourly rate which was higher for the specialist and GP than the payer. The justification for the higher daily rate for payers was due to the difficulty in recruiting such people. The Panel noted that each of the four integrated healthcare specialists had to complete one payer call (each call cycle was 50 minutes in duration). All consultants were paid for a full day. The event started at 8.30am and according to AstraZeneca's submission was finished by 3pm.

The email from the training service provider to a third party agency set out the details of payment for health professionals/payers for the meeting in question and another. The email stated that GPs were to be paid £500, and 'if you get some that are grumbling then up it'. The facility to increase payment applied to all of the fees for health professionals/payers. The payments were referred to as incentives which the Panel considered was an unfortunate choice of word given that the fee was supposed to be payment for a service that fulfilled a legitimate need.

The Panel noted that the invitation from the training service provider referred to the aim of the event which was to provide feedback to medical

representatives, complimentary lunch and refreshments. The invitation stated that the training service provider was working on behalf of 'a leading pharmaceutical company' but further details were not given. The reply form was not clear in that regard.

The Panel noted that the service agreement forms stated that the service was to assess representatives' training. It was not clear that the training service provider was working on behalf of a pharmaceutical company.

Taking all the circumstances into account, the Panel did not consider that the event was a *bona fide* training event. The Panel was concerned about the scale of the activities and that representatives were being assessed by customers upon whom they might be expected to call, in the absence of safeguards. The Panel noted its concerns set out above and taking all of the circumstances into account considered that the training session was promotional. It was disguised in this regard and a breach of the Code was ruled.

The Panel noted its ruling above that the event was disguised promotion and considered that any payment to attend was therefore in breach of the Code.

The Panel recognised the need to use health professionals as consultants in the training of representatives, and that some of the information collected at the event in question could lead to professional development plans for the representatives participating. It considered that the criteria for selecting the complainant was related to the need for the service and ruled no breach of the Code. The Panel did not consider that the level of the payments for the payers and the hot desk together with the implication that all payments could be increased by the agency following adverse comment from those invited met that criterion. The Panel also noted its comment above that the event was not a *bona fide* training event. The Panel noted its ruling above of a breach of the Code in relation to the payment of honoraria for an event that was considered to be disguised promotion. The Panel considered that the arrangements thus failed to satisfy the requirements for the hiring of consultants and a breach of the Code was ruled.

The complainant had made a general allegation regarding the Code requirements for the declaration of payment of fees. The Panel did not consider that this was relevant. No breach of the Code was ruled.

Upon appeal by AstraZeneca the Appeal Board considered that the use of health professionals in the training of pharmaceutical company personnel was a legitimate activity. The question to be considered in this case was whether any promotion as a consequence of this training was necessary as part of the training, proportionate to the training element of the activity, and transparent. The first element to be considered was whether the activity was disguised promotion.

The Appeal Board noted the invitation to the complainant was titled 'Training Day Research invitation'. It stated that the author was 'conducting a study with specialists and medical reps' and that the 'research' would involve 'mock consultations with reps as well as doing some group and individual exercises'. The invitation stated that there would be a £600 payment. The Appeal Board considered that the invitation to the complainant was poorly written. It could imply that the recipient was being invited to a market research event for which they would be paid. The fact that the recipient was being invited to help train and assess the performance of representatives was not clear.

The Appeal Board noted that in 2011, 11 regional CDC events had used 206 health professionals to train 304 representatives. The Code referred to the use of health professionals and appropriate administrative staff as consultants and advisors, provided that, *inter alia*, the number of consultants retained was not greater than the number reasonably necessary to achieve the identified need.

The Appeal Board noted AstraZeneca's submission that it had not decided on the numbers or individual identities of health professionals used. The Appeal Board noted AstraZeneca's submission that geographical factors affecting the required number of health professionals needed did not just relate to the devolved nations, but to different specialisms in a number of regionally distinct health economies. In addition regionally held events had increased the overall number of health professionals needed. The Appeal Board noted AstraZeneca's submission that three assessed calls were necessary to provide a fair assessment.

The Appeal Board noted AstraZeneca's submission that health professionals were briefed by the training service provider on the morning of the meeting and told that this was an AstraZeneca event. It was made clear that the objective of the day was assessment and training.

The Appeal Board noted from AstraZeneca that the service agreement contracts were completed on the day of the event. Health professionals also completed a profile form which required them to state their clinical area of interest, current prescribing habits and 'AstraZeneca Brand Awareness' (none, low, moderate or high) for five of AstraZeneca's medicines. These forms were then copied to each representative to enable them to prepare a profile. The Appeal Board noted from AstraZeneca that it was necessary for representatives to be judged on how they detailed the medicines that they normally promoted so

that assessed calls were as close as possible to 'real world' calls in the field.

The Appeal Board noted that although the assessment could last either 15 minutes (representatives) or 30 minutes (integrated healthcare specialists), these were the maximum times allowed and calls could be shorter. AstraZeneca had submitted that the maximum call lengths were appropriate and reflected actual call times in the field.

The Appeal Board noted AstraZeneca's submission that because of difficulties in recruitment, it had given the training service provider the names of 19 health professionals to approach to participate. The training service provider had handled the recruitment and two of the 19 attended the subsequent CDC. At that meeting two representatives had been seen twice by the same health professional as three health professionals had unexpectedly failed to attend.

The Appeal Board considered that an unavoidable consequence of the training event would be the promotion of AstraZeneca's products but that the consultants' attention would be focused on providing information about the representative's performance, not on receiving promotional messages. The Appeal Board noted that AstraZeneca submitted that it had not monitored any subsequent changes in the prescribing habits of the participating health professionals.

The Appeal Board noted that the email from the training service provider to a third party agency set out the payment details for health professionals/payers for two of the meetings. The email stated that GPs were to be paid £500, and 'if you get some that are grumbling then up it'. The facility to increase payment applied to all of the fees for health professionals/payers. The Appeal Board noted that AstraZeneca acknowledged that the wording in the email was unfortunate, but the company stated that in fact none of the health professionals used in the CDC events were paid more than the maximum rates stated (£500 for GP; £600 for specialist and £700 for payer) and that these amounts were fair market value rates.

The Appeal Board noted AstraZeneca's submission that events held in January 2011 were not CDC but separate training for a new product launch. The CDC was an annual event.

The Appeal Board noted from AstraZeneca that that the purpose of the CDC was to up-skill its representatives to meet the requirements of the NHS. AstraZeneca submitted that it had been able to demonstrate an improvement in sales force performance since starting CDC assessments and training.

Taking all the circumstances into account, the Appeal Board considered that on balance the event was a *bona fide* training event. Although the Appeal Board was concerned about the poor wording in the emailed invitation, it did not consider that the CDC training meeting was disguised promotion. The Appeal Board ruled no breach of the Code. The appeal on this point was successful.

The Appeal Board noted its ruling above that the event was not disguised promotion; the payment to attend was a genuine consultancy fee and so was not in breach of the Code. No breach of the Code was ruled. The appeal on this point was successful.

The Appeal Board noted the comments above about the complexity of the meeting and the requirement for a large number of health professionals and it considered that on balance the arrangements were acceptable and no breach of the Code was ruled. The appeal on this point was successful.

A hospital doctor complained about an invitation which she had received to participate in a day-long workshop in June 2011 which would include, *inter alia*, mock consultations with representatives. The invitation had been sent by a market research agency on behalf of AstraZeneca UK Limited.

The invitation in question was headed 'Training day research invitation' from a third party agency stated that it was 'conducting a study with specialists and medical reps. The research involves a day long workshop which includes running mock consultations with reps as well as doing some group and individual exercises'. The research was to run from 8.30am until 5pm. The aim was to improve representatives' performance and gain feedback on what 'would make rep visitations more useful …'. Participating health professionals would receive £600 for taking part. The invitation stated that 'The research is also purely an exercise so in no way will any element of day be promotional'.

COMPLAINT

The complainant stated that the invitation was clearly not targeted to her for her specific expertise since she was not an expert in training sales representatives. The complainant noted that on the invitation her name had been spelt incorrectly and that she had been asked to recruit any colleagues to attend. The complainant alleged that this approach was in breach of Clause 20 of the Code.

The complainant replied to the invitation stating that these events were 'rather sophisticated attempts to get doctors to listen to the same marketing information repeatedly, getting round the problem of paying doctors to become brainwashed, by calling it rep training'. The complainant stated that this was ethically dubious.

When writing to AstraZeneca, the Authority asked it to respond in relation to Clauses 12.1, 18.1 and 20.1 of the Code.

RESPONSE

AstraZeneca submitted that the training event in question formed part of a larger in-house programme of activities called Competitive Capabilities. The objective of the Competitive Capabilities programme, which began in 2010, was to upskill the AstraZeneca sales force across multiple capability areas. The programme was AstraZeneca's single largest current investment in developing its employees and to date had involved over 700 sales force members.

The programme consisted of multiple different initiatives and was focused on developing the capabilities of the sales force from training on coaching and performance management for managers through to in-call effectiveness and excellence in product knowledge for representatives. Through such interventions AstraZeneca set out to better meet health professionals' needs by helping representatives to add greater value to their interactions with them.

The training day in question was a Capability Development Centre (CDC) event: a key component of the Competitive Capabilities programme. A CDC was a training event which supported the upskilling of AstraZeneca representatives through objective assessment of call performance, conducted in a safe training environment allowing them to practise and learn. In order to ensure the training environment was as realistic as possible, health professionals, usually GPs or consultants with the relevant therapy area expertise, were engaged as consultants to participate in assessed calls with representatives. For these events, the use of such consultants was vital to ensure that the company objectively evaluated the capabilities of its representatives in an environment which recreated, as closely as possible, a realistic representative/health professional interaction, whereby the consultant asked questions typical of a normal call. It was not possible to achieve the same outcome using actors or by engaging in role play with other representatives, methods also used in representative training events. Consistent with a training activity, the outputs from a CDC event supported individual development plans and direct interventions designed to improve further the representative's capability levels.

AstraZeneca explained that using health professional consultants at such training events was a well established practice in the pharmaceutical industry and one of the most robust and objective ways for companies to accurately assess the capability of its employees and support their development. Indeed, since 2007 the training service provider , who conducted the event in question on behalf of AstraZeneca, had worked with over 50 clients from different pharmaceutical organizations and run over 250 sales force effectiveness events, many of which had involved the use of health professionals as consultants in a similar way to that described above, with no complaints.

The training day in question was one of eleven similar regional events conducted for AstraZeneca in June 2011. As a result, 304 primary care medical representatives and integrated healthcare specialists completed the training and 206 health professionals were involved across the country. AstraZeneca provided details on all eleven events including the number of health professionals used at each event. All of the events took place in independent venues; hospitals or GP surgeries were not used. A further mop-up training event was planned for later in the summer for representatives who were unable to complete one of the other events. AstraZeneca had a further eleven events planned for later in 2011 focusing on the needs of specialist care.

Methodology used in the June CDC series

AstraZeneca submitted that the success of the training events was underpinned by a rigorous assessment process which was completed for each representative. This was critical to enable representatives to measure progress against previous development plans shaped by their previous CDC assessments and also to update individual development plans which would continue to be measured, tracked and assessed on an ongoing basis.

The terms defined below were those used to describe the profiles of those who took part in the June series of CDC events:

- Delegate: an AstraZeneca representative (primary care) or integrated healthcare specialist (secondary care).

- Observer: an employee of the training service provider, an external contractor or an AstraZeneca sales manager who observed and assessed the performance of each delegate in assessed calls.

- Assessor: a health professional either a GP, specialist or payer contracted to the training service provider as a consultant for the delivery of a CDC event. Also referred to as a consultant.

- Hot desk consultant: a health professional consultant who was available to support representatives or integrated healthcare specialists to prepare for assessed calls. This was a key role and, importantly, hot desk consultants also covered for non-attendance or late cancellations by health professionals scheduled to participate by being re-assigned as assessors when required.

Description of approach to CDC calls

The core training element of the June CDC series was the assessed call, designed to simulate real life by using health professionals contracted as consultants who had the same type of clinical expertise as those health professionals on whom

the representative would normally call. Therefore based on these requirements for representatives GPs were chosen and for integrated healthcare specialists, cardiologists, diabetologists, respiratory physicians, rheumatologists, and payers, (eg pharmaceutical advisors) were chosen.

Due to the nature of the CDC and the assessed call neither previous relevant training experience nor any additional expertise was required for a health professional selected for this activity.

Each CDC event took place over one day during which delegates had to deliver three assessed calls. For the representative this was three GP calls and for the integrated healthcare specialist this was two specialist calls (cardiologist, diabetologist, respiratory physician and/or rheumatologist) and one call with a payer. The materials used by the representatives and integrated healthcare specialists in the assessed calls were the approved campaign materials for the products that they currently promoted ie those that they would use in an actual call.

For each call cycle there was a delegate (representative) and assessor (health professional consultant) as well as an observer. These individuals participated in call cycles through the stages set out below:

Stage	Duration Medical representative call (minutes)	Duration for integrated healthcare specialist call (minutes)
Assessed call	15	30
Verbal feedback from health professional assessor	5	5
Completion of assessment forms by observer and assessor	5	10
Change over	5	5
Total duration per call cycle	**30**	**50**

Therefore the duration for a full call cycle with a representative was 30 minutes and 50 minutes for an integrated healthcare specialist. This provided sufficient time for detailed evaluation and assessment to be completed for each call.

Evaluation and Feedback Process

For each call the observer completed an in-call effectiveness evaluation form which assessed the delegates' performance across the following areas:

- Open and identify/clarify needs
- Engage customer in compelling proposition – skills
- Engage customer in compelling proposition – knowledge
- Close and agree joint and future actions
- Overall impact
- Emotional intelligence

Under each of these areas the delegate was scored on a scale of 1 – 4 against a series of questions which map to one of the areas above. The scale was defined as:

- Score 1 = Poorly demonstrated or not demonstrated at all – clear area of weakness
- Score 2 = Some evidence but opportunity for improvement
- Score 3 = Good demonstration of skill (meets management ambition)
- Score 4 = Excellent demonstration of skill – a clear area of strength

In addition to the observer assessment completed following each call, the assessor also had to complete a feedback evaluation form. This consisted of the following six areas:

- Did the individual understand your current prescribing habits/areas of interest?
- Did the individual have a good level of knowledge around therapy area/brand/competition?
- Did the individual tailor the discussion according to your needs?
- Would you act differently as a result of this conversation?
- Has the individual delivered a genuine value in this interaction?
- Would you see this individual again?

For each of these areas the health professional assessor would score the performance of the representative from 1 (strongly disagree) to 4 (strongly agree) with the opportunity to provide more detailed comments.

On the day the representative was given photocopies of the completed assessment forms for all three assessed calls and also an overall summary form containing the averaged scores from all their calls. Following the event, individualised reports summarising their performance, compared with previous performances in other CDC events were produced. These would be sent to all delegates to help them update their individualised development plans. Such a strong focus on feedback and rigorous evaluation in this series of events was consistent with a high quality training intervention.

The description of the events and assessments given above clearly demonstrated that the objective of the CDC events, including the event in question, was solely to assess the representative call for training purposes and not a 'rather sophisticated attempt to get Doctors to listen to the same marketing information repeatedly' as alleged by the complainant.

Selection of consultants for CDC event in June 2011

In line with the general description of the June CDC series above, the objective of the event in question was to complete a one-day capability assessment event for the local representatives and integrated healthcare specialists. The requirements for the

event were similar to those for the other events in the June CDC series including that each delegate complete three separate assessment calls with consultant health professionals of that relevant speciality background. Thirteen representatives and four integrated healthcare specialists were scheduled to complete the event. This therefore required a total of 39 representative assessed calls and 12 integrated healthcare specialist assessed calls to be completed on the day.

For this event, the training service provider recruited 17 health professionals with the required clinical expertise (GP, cardiologist, diabetologist, rheumatologist, respiratory physician and payer). The required expertise was that the health professionals had the required understanding of the therapy area concerned and worked in the same type of setting upon which representatives would normally call. The consultant health professionals chosen had to be available for the full day; health professionals who had been recruited were expected to either participate in the CDC call cycles relevant to their area of clinical expertise and/or were assigned to the hot desk area where they were required to support the preparation by the representatives or integrated healthcare specialists for the assessed calls as appropriate. AstraZeneca noted that of the 17 health professionals recruited, on the day only 13 health professionals attended; the training service provider was not informed in advance that four would not attend. Non-attendance on the day of in excess of 10% of the consultants was common.

The CDC project proposal and associated contractual terms and conditions between AstraZeneca and the training service provider ensured that those health professionals recruited had the required relevant clinical expertise. The training service provider briefed two agencies to help recruit consultants with the relevant clinical expertise. Due to ongoing challenges near the date of the event in recruiting a sufficient number of consultants, two health professionals recruited for the event were referred to the training service provider by members of the AstraZeneca sales team. One health professional was recruited by the training service provider and the two agencies recruited 10 health professionals.

AstraZeneca noted the complainant's concern regarding the fact that the invitation stated that the recipient was free to forward the letter to any colleague including registrars that might be interested. In all cases, any respondents to this invitation were followed up to confirm that they had the relevant clinical expertise before recruitment to the training event was completed.

Consultant payment rates for the CDC event in June 2011

Payment rates used for the recruitment of all 17 health professionals were determined by the training service provider based on one-day's work at this type of training event. The fair market value daily rates for the 17 health professionals recruited for the event were GP £500, specialists £600 and payer £700.

These consistent and competitive rates were used by the training provider and were based on years of experience of working with other UK pharmaceutical companies to run events involving the use of consultants such as sales force effectiveness meetings. The training provider determined these rates through referencing the rates used in other contexts such as for speaker events, clinical research and private healthcare delivery. AstraZeneca submitted that these fair market values were similar to those included in a separate proposal received for the same project from another independent provider of sales force effectiveness solutions.

Although AstraZeneca's in-house recommended consultant fair market value rates did not have a specific category for this type of training event, the AstraZeneca guidelines on consultant payments set maximum hourly consultancy rates and details were provided. AstraZeneca submitted that the rates were in line with those used for this project.

Consultancy services agreement applicable for the CDC event in question

The consultancy services agreement applicable to the event in question was provided. All 13 health professional consultants who participated completed the necessary services agreement.

Account of the CDC event

In addition to the 13 representatives and four integrated healthcare specialists, there were four AstraZeneca managers, two external contractors and two members of the training service provider team who acted as observers.

Areas of the hotel booked for the event included a briefing room for health professionals, a briefing room for delegates and observers, an administration room as well as several rooms converted to mimic health professional consultation rooms.

The planned schedules for the event were provided although changes were made on the day. The amended schedule based on the recollection of the executive who had overall responsibility for the day's schedule was provided. Breaks were taken throughout the day and included light refreshments and a sandwich lunch.

Health professionals were separated from delegates and observers before the event. Health professionals were briefed separately to the delegates and observers and provided with a registration pack which contained:

- Representative and integrated healthcare specialist schedules

- Hints and tips document
- Customer evaluation form
- Services agreement
- Payment details form

The health professional briefing session was delayed 15 minutes until 8.45am due to late arrival of several health professionals. The briefing was given by an employee of the training service provider using the presentation Customer Briefing June 2011. The briefing covered:

- Objectives of the meeting: to assess and evaluate the selling skills of representatives and integrated healthcare specialists
- Service agreement and payment form
- Hints and tips for the day including adverse event reporting requirements
- A run-through of the schedule for the day
- Requirements for consultants who would be in one of the interview rooms and also for consultants who would be assigned to the hot desk room during the course of the day
- Housekeeping

Following the briefing, signed and completed agreements and payment forms were collected by the training service provider team. The health professional briefings were completed at 9.10am and following this the remainder of the day was dedicated to completion of the three assessed call cycles for each of the 17 delegates. After the briefing session the consultants were then taken to an interview room or remained in the hot desk area as assigned on the day.

An AstraZeneca business manager briefed the delegates and observers, separately to the health professional consultants, on the purpose of the training day and its place within the overarching Competitive Capability programme. The delegates were then briefed by a senior manager from the training service provider. Copies of the two presentations were provided. The topics covered were schedule, duration and procedures for each call, housekeeping and use of the hot desk consultants to support preparation for the assessed calls by the representatives and integrated healthcare specialists.

AstraZeneca delegates were also given a delegate/observer pack which contained, schedules, name card, sticky labels, hints and tips document and health professional profile.

Each delegate had to complete three calls on the day: three GP consultant calls for each representative and two clinical calls (cardiologist, diabetologist, rheumatologist, or respiratory physician) and one payer call for each integrated healthcare specialist.

Only one product was to be discussed in each call using the current campaign materials and included electronic interactive detail aids, hardcopy sales aids as well as other certified promotional materials as appropriate.

On the day in question, 51 assessed calls were completed. The 13 representatives completed 39 calls and 12 calls were completed by 4 integrated healthcare specialists.

To complete the above number of assessed calls, four GP consultants assigned to assess calls each completed 9 or 10 call cycles with representatives. Similarly the consultant group participating in assessed calls with the integrated healthcare specialist group (cardiologist, diabetologist, rheumatologist, respiratory physician or payer) each completed two call cycles. The three other consultants who were assigned on the day to the hot desk area supported the preparation by the representatives and integrated healthcare specialists for the assessed calls. During vacant slots assessors were also available to provide additional support for representatives in preparations for assessed calls.

During the slots where delegates were not scheduled for assessed calls, they could either stay in the delegate briefing room or go to the hot desk room to work with one of the hot desk consultants to prepare for their next assessment.

To further simulate the real life situation, representatives were provided with summary health professionals' profiles for the consultants recruited to the event which included information collected from the health professionals by the training service provider either before the event or on the day. The information was not collected by the AstraZeneca sales team. The profile information was provided to support effective pre-call planning thus enabling the representatives and integrated healthcare specialists to better tailor their interaction to the specific needs of the consultant in a particular call.

After each representative had completed all their assessed calls, they were given copies of the completed assessor evaluation forms and observer-completed call effectiveness forms for each of their calls and also an overall summary report based on the observer scores for all three calls. In addition each representative had their calls video-recorded as an additional personal resource to further support their development.

Experience from previous events, both CDC and non-AstraZeneca programmes identified that there was usually a moderate to high rate of health professionals' non-attendance on the day. Four health professionals did not attend the event as originally planned and the training service provider was not informed of these non-attenders prior to the event. For the representative schedule one GP did not attend and this was accommodated by removing this health professional from the hot desk list. For the integrated healthcare specialist schedule, three health professionals did not arrive: two diabetologists and one cardiologist. Therefore on the day re-assignment of hot desk consultants to

the assessor group was required including reassignment of the hot desk diabetologist to assess the two calls where a diabetologist was required. Non-attendance was common at such events and illustrated the need for substitution on occasion of hot desk consultants into the assessor pool – thus the hot desk consultants acted as both a resource for representatives preparing for assessed calls and as assessor health professional consultants if required.

Sales representatives could leave after completion of their three assessed calls and once they had received copies of their completed feedback materials. Although contracted for a full day, consultants were released when their services were no longer required for the successful completion of the training event.

These events were specifically designed to try to ensure that each representative completed three separate calls with three different consultants, but due to non-attendance by health professionals on the day, this was not possible in all cases, as two of the four integrated healthcare specialists had to have assessed calls with a consultant that they had already worked with on the day. Nevertheless, all 51 assessed calls were completed by approximately 3pm at which point the meeting ended.

Additional comments on Clauses 12.1, 18.1 and 20.1

Clause 12.1: Promotional materials and activities must not be disguised

As detailed above, the CDC series of events in June including the event in question were clearly legitimate training activities and were not promotional activities (either overt or disguised). The June CDC series of events were a rigorous training intervention held in a non-health professional practice environment. The clear objective of the event (which was achieved) was to complete a capability assessment activity in a simulated real life environment which involved three assessed calls for all the representatives and integrated healthcare specialists. As stated above, health professional consultants for this event were required to ensure the creation of a call environment as close to reality as possible. Only consultants with the relevant clinical expertise for the assessed calls were chosen for the event (GP, cardiologist, diabetologist, respiratory physician, rheumatologist or payer). In addition, there was detailed feedback and evaluation conducted on the day and the outputs from the event had been used to support the development plans for individual representatives including summary reports detailing their progress over the entire Competitive Capabilities programme to date. This detailed and very specific training programme reinforced that this was a legitimate training event and not either overt or disguised promotion as alleged.

On the day, briefing information provided to delegates and assessors and hot desk consultants also made very clear that this was a training event. All service agreements were signed and in place for the 13 consultants who participated and each clearly referred to the fact that this was a training event.

The detailed information above demonstrated that this was a legitimate high calibre training programme and not disguised promotion.

Clause 18.1 No gift, benefit in kind or pecuniary advantage shall be offered or given to members of the health professions … as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine …

As demonstrated above, this was a legitimate representative training event and not an activity which would constitute an inducement. All 13 health professionals completed and signed service agreements confirming their understanding that this was a one day training event. Briefings on the day made clear that this was a training event and also explained unequivocally what was required from consultants. Payment of consultants for this event was based on fair market value and consultants were chosen on the basis of their clinical expertise to support the training event. All payments were made to health professionals in relation to their active participation during the training event and for any appropriate travel expenses incurred in order to attend the event. This was not an inducement to prescribe, supply, administer, recommend, buy or sell any AstraZeneca medicine. Since 2007, having run more than 250 events involving several thousand health professionals, the training service provider had confirmed that it had never received a complaint from health professionals attending one of these meetings that the event was anything other than a training activity.

Clause 20.1: HCPs … may be used as consultants and advisors … for services … including training ….

The engagement of health professional consultants for the event represented a genuine consultancy arrangement in the provision of a training service as set out in Clause 20.1. This CDC event clearly represented a legitimate training event and formed part of the overall training plan for the Competitive Capabilities programme. Written and signed contracts were in place between the training service provider and all 13 consultants on the day of the meeting before the commencement of the assessment calls. A copy of one signed services agreement was provided.

Consultants for the event in question were selected according to the clinical expertise required to complete the training intervention. As explained above, in order to meet the requirement to have a realistic training environment, the selection criteria for this assignment was that the consultants had clinical expertise in one of the following areas: GP, cardiologist, diabetologist, rheumatologist,

respiratory physician or payer. For this type of training event no additional criteria were required. AstraZeneca submitted that all the consultants employed at the event met these selection criteria. Indeed, the complainant in this case, as a consultant diabetologist, would have also met the required criteria.

Seventeen health professionals were chosen for the event, 13 of whom participated as consultants. From the 17 health professionals scheduled for the event, there were eight GPs: four GPs were scheduled to complete 39 x 30 minute call cycles and four were scheduled to support preparations by the 13 representatives for the assessed calls in the hot desk area.

Nine of the health professionals scheduled for the event were specialists (cardiologists, diabetologists, rheumatologist, respiratory physicians and payers) and they were also split between the assessed calls and hot desk groups to support 12 x 50 minute call cycles for the integrated healthcare specialist. The higher ratio for the number of specialists to representatives for the integrated healthcare specialist group was because five different expert groups were recruited so that each integrated healthcare specialist was able to complete three different calls with three different consultants relevant to the therapy area/setting for products which they would normally promote (cardiology, diabetology, respiratory medicine, rheumatology and payer). On the day, three consultants allocated to the integrated healthcare specialist group did not attend which unfortunately resulted in two out of four integrated healthcare specialists having to do repeat assessed calls with the same consultant.

AstraZeneca recognized that ideally, the integrated healthcare specialist call cycles should be programmed to minimize the time that health professional consultants were required and contracted. Due to the complexity of the programme, a whole day was the minimal planned period required in practice. Therefore the number of consultants recruited for this event was consistent with the number considered to be reasonably necessary to achieve the training objective for this event.

Finally, as stipulated in Clause 20.1, the services agreements signed by all 13 consultants included the following provision regarding the obligation relating to declaring their work as a paid consultant: 'You warrant that you shall, whenever you represent us in public about a matter which is the subject of this Agreement or any issue relating to us, declare the nature of this Agreement, and the fact that you act as a consultant to us in the manner specified within this Agreement.'

Therefore, the requirements of Clause 20.1 were fully addressed for the CDC event in question.

In summary, AstraZeneca stated that this was a legitimate training event as part of a structured training programme, underpinned by appropriate arrangements and consultancy service agreements. AstraZeneca deeply regretted the allegations raised by the complainant who clearly felt strongly about the issue and AstraZeneca's perceived intent. However, AstraZeneca considered that its intent was transparent, appropriate and legitimate and that it had responded fully to the concerns raised particularly with regard to the challenges raised with respect to Clauses 12.1, 18.1 and 20.1. The company denied that there had been any breach of these clauses.

In response to a request for further information, AstraZeneca pointed out that it did not have one single overarching briefing document with the training service provider for this training programme. Instead briefing between the two organizations was built and evolved through regular communications which resulted in an industry leading training programme in terms of the outputs and development plans described above.

The business relationship between AstraZeneca and the training service provider was not a 'contracting-out' relationship, but a 'preferred partner' relationship. The two companies worked in partnership to deliver the CDC event series. In addition to a close working relationship, a number of documents supported the agreement between AstraZeneca and the training service provider, copies of which were provided:

- SFE Standard Terms and Conditions MR/HIS ad FLSM CDC AstraZeneca
- Presentation given to AstraZeneca by the training service provider at the design phase outlining potential options for the CDC project
- Document shared with the training service provider setting out the ambition for the project in terms of up-skilling AstraZeneca's medical representatives and integrated healthcare specialists
- One of the project estimates from the training service provider for the regional CDC events
- Email summarizing one of the AstraZeneca briefing meetings

This close working relationship between the two companies through both frequent and informal briefings underpinned with additional documents above had enabled the two organizations to work closely and quickly together to complete the June CDC training events, involving a total of 910 assessed calls and a total of 304 representatives. To have successfully completed this project over such a short period of time was testimony to the success of this working model.

In response to a request for more information in relation to briefings provided by the training service provider to the two agencies it used to help recruit consultants with the relevant clinical expertise, AstraZeneca provided a copy of the client programme agreement in place between the training service provider and a third party agency,

one of the agencies for this assignment, the contractual agreement in place between the training service provider and the other agency and an email from the training service provider to each of the agencies.

AstraZeneca provided examples of the adapted standard invitation letter from the training service provider used for recruitment of health professionals from the training service provider pool. Also provided were copies of email invitations sent by the training service provider to health professionals who had been provided by AstraZeneca very near to the date of the event to support the ongoing recruitment challenges. AstraZeneca submitted that all these invitations made very clear that the purpose of the event was for representative training and also what fee would be paid for participating as a consultant for these events.

AstraZeneca confirmed that the email invitation sent to the complainant by one of the agencies engaged by the training service provider to help recruit consultants had not been examined or certified by AstraZeneca. AstraZeneca noted that the initial letter from the Authority did not ask it to respond to Clause 14.3. There was no requirement set out in this clause for an invitation of this nature to be either certified or examined by the relevant pharmaceutical company. For this project, neither AstraZeneca or the training service provider reviewed the invitation prior to use. However, on review of the invitation AstraZeneca acknowledged that the use of terms such as 'study' and 'research' were classically associated with market research activity rather than a training event. Nevertheless, AstraZeneca considered that the subject of the email invitation 'Training day research invitation' as well as other language and statements used in the body of the email such as 'running mock consultations with reps' and 'aim of the workshop is not only to aid in improving reps performance but also to gain feedback on what would make rep visitations more useful for health care professionals' left the reader in no doubt that the email constituted an invitation for a consultant to support representative training activity. Even the complainant referred to the activity as 'rep training' and understood to what activity the invitation pertained. In addition, AstraZeneca submitted that it was important to be clear that the health professional complainant had not referred to use of the terms 'study' or 'research' but rather that this complaint related to allegations of disguised promotion and inappropriate use of consultants.

An AstraZeneca global initiative, implemented across all AstraZeneca markets in the summer of 2011 set out to further drive standards in all its external interactions. AstraZeneca UK was now implementing additional controls and processes to ensure that either bespoke or template invitations to health professionals for similar training events in the future were formally reviewed prior to use. This applied to invitations for other similar training events, for invitations sent either directly or indirectly via contractors.

AstraZeneca also confirmed that the training service provider was also in the process of updating its standard operating procedure (SOP) for such activities to ensure that in the future any communication sent out by third parties, including screening documentation, would be controlled documents, approved by the training service provider and also by the client prior to use.

AstraZeneca reminded the Authority that despite these considerations, it was the company's view that there was no Code requirement that such invitations were examined or certified before use and that it was important to consider the overall legitimate training objective for this series of events which was met through the successful completion of 910 assessed calls with 304 representatives thereby supporting the individualized development plans which would result in the further up-skilling of the AstraZeneca primary care sales teams.

In a response to a request for further information on the role of the 'hot desk' consultant, AstraZeneca reiterated that the hot desk consultant was available on the day to support medical representatives or integrated healthcare specialists in preparing for assessed calls. This was a key role in such events to support the preparations of representatives for assessed calls. The hot desk consultants also played an important role in covering for non-attendance or late cancellations by health professionals scheduled to participate at such events by being re-assigned as assessors when required.

AstraZeneca submitted that it was clear from the feedback on the event in question that the hot desk health professionals were seen as an invaluable resource by the representatives in helping them prepare for assessed calls on the day. Examples of discussions that took place at the event between the 'hot desk' consultants and representatives included topics such as:

- Information which health professionals found useful to be communicated in calls
- Feedback on challenges that a representative might have encountered in one call so that they could better prepare for the next
- Practice sections of the call such as call opening
- Understanding of current events in the NHS to help ensure that assessed calls were more aligned with a health professional's agenda

As stated above, a key role of the 'hot desk' health professional was to be an additional resource available to support preparation for subsequent calls and therefore representative interaction on the 'hot desk' health professionals was not assessed.

AstraZeneca submitted that it was important to note that, in most cases, health professionals were recruited to provide a service to support the delivery of the training event and not specifically

recruited to either the assessor or hot desk roles. The training service provider had confirmed that although allocations to the two different roles were made on a provisional basis prior to the meeting, final allocation was only made on the morning of the event, as in the meeting at issue, based on any levels of non-attendance on the day by scheduled health professionals.

In addition, on the morning of the event at issue, as part of the briefing, the purpose of the hot desk health professionals was made clear to the representatives. A copy of this briefing presentation was provided.

In response to a request for the reasons for the difference in fee between health professionals and payers, AstraZeneca reiterated that payment rates used for the recruitment of all 17 health professionals were determined by the training service provider and were based on one day's work at this type of training event. The fair market value rates for the 17 health professionals recruited for the event were as stated above.

Whilst AstraZeneca recognized that its fair market value rates indicted a lower hourly rate for payers, lower than both that indicated for GPs and consultants and that offered by the training service provider, it is important to note that the total paid to payers is in line with AstraZeneca fair market values and therefore not considered excessive.

As could be seen from this project there were modest differentials between the fees determined for GPs, specialists (cardiologists, diabetologists, rheumatologists, respiratory physician) and payers. However, this was based on fair market value rates for recruitment to these types of activities. The training service provider also confirmed that based on its experience of conducting similar events previously that recruitment of payers to such events was relatively more difficult that for many other types of health professionals hence the fair market value levels set by the training service provider and determined as appropriate for this project.

Health professionals were contacted to provide a service at the June CDC training events and were required to be available for the duration of the day of the event. Therefore health professionals were paid the same rate irrespective of whether on the day of the event they were assigned to be an assessor or a hot desk health professional.

In response to a request for details of the outcomes/learnings for each representative, AstraZeneca submitted that on the day, after the representatives had received copies of their completed assessor evaluation and observer call effectiveness forms, there was no further discussion of the results; these forms were given on the day so that representatives could immediately start to reflect and incorporate some of the learnings in to their own development plans. In addition, managers had also been provided with one page summary report forms for each of the representatives who participated in the event. Copies of all 17 summary report forms for those participating in the event at issue were provided. Over the summer, these materials would be used to support discussions between manager and representatives right across the UK to underpin development of refined development plans which were maintained in the AstraZeneca internal 'MyCoach' application as individualized development summaries. The consequent 'development' contracts could be tracked and reviewed at subsequent field visits with further interventions implemented as required. As the event had only recently been conducted, this process was still ongoing across each of the regional teams in the UK.

In terms of current status for the team who attended the event at issue, all four team members of the integrated healthcare specialist team had now completed initial one-to-one meetings with senior AstraZeneca managers at post-event reviews of their performance at the CDC event. Further one-to-one reviews with each of the integrated healthcare specialist team was also planned for later in the summer to build on these initial development discussions. The 13 medical representatives who completed the training event on 20 June would be also followed up with their manager during August.

Outcomes and learnings for each representative could be easily seen in the summary reports provided to the Authority by AstraZeneca for all 17 representatives who participated at the event in question.

AstraZeneca submitted that the above description of some of the follow-up interventions, the technological platform to support the capturing and tracking of plans, in addition to the detailed methodology and assessment process for assessed calls at the CDC events previously described, clearly marked this out as a legitimate industry-leading training activity which would support the up-skilling of AstraZeneca medical representatives and integrated healthcare specialists as part of the overarching Competitive Capabilities Programme.

In response to a question as to whether the representatives were from the same geographical area as the health professionals recruited to participate, AstraZeneca submitted that in the design phase for the June CDC project it was decided that there would be 11 regional training events spread across the four UK nations. This was very much driven following feedback and learnings from the national CDC event series which took place in 2010; key considerations for a regional CDC series were:

- Regional events very much supported assessed calls in a far more 'realistic' environment than would take place at a national event. At the previous AstraZeneca national event in 2010 run by the training service provider there were situations where representatives were allocated

to complete assessed calls with health professional consultants who worked in a very different healthcare setting. For example, English representatives allocated to health professional consultants from one of the devolved nations, where healthcare priorities were different. Therefore, the regional approach enabled far more realistic setting for assessed calls to take place supporting the overarching training objective.

- Following on from feedback from a previous national event, regional events could often be a less stressful environment for many representatives thereby facilitating them to complete their assessed calls in a manner more likely to be similar to the way in which they would conduct their normal calls in their daily work.
- From a logistical perspective, regional events also support the recruitment of health professionals from the region as well as representatives who were also based in that particular region, reducing the amount of time off the road and away from clinics, respectively.

Due to the regional format of the event, as with other events in the series, there was a chance that a health professional consultant could be asked to assess a representative who called upon them in their normal employment. Importantly, the allocation of health professionals to a particular assessed call in the schedule with a representative was conducted by the training service provider without knowledge of AstraZeneca's sales territories or customer contacts. AstraZeneca confirmed that at no point was such information shared with the training service provider for the purpose of the CDC series. Although AstraZeneca recognized the potential concerns of the Authority regarding regional events of this type, it was important to understand that such a regional approach was a key way to support meeting the training objective based on creating a realistic environment so that the true underlying skill and capability of the representative could be objectively and accurately assessed.

In response to a request for more information in relation to how representatives were instructed to identify potential health professional participants, AstraZeneca submitted that in the final weeks prior to the event in question, the training service provider team were still required to recruit additional specialists. Only as a result of the recruitment challenges faced by the training service provider did the business manager offer to support the final stage of recruitment. Following acceptance of this offer, the business manager asked three members of his team to provide a list of potential suitable health professionals. This instruction was given by telephone and explained that certain categories of specialists were required for the event. Following this, lists of names (a total of eight respiratory physicians and 11 payers) were sent to the business manager who then in turn forwarded these to the training service provider for evaluation as to suitability for recruitment to the event. Of the final 17 health professionals who were recruited, only two were sourced in this fashion. At no point were the representatives instructed to identify names of potential health professionals as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. This course of action was undertaken solely to address the recruitment challenges faced by the training service provider in the run-up to the event in question and not for any other purpose.

In response to a question as to where in the contract with a health professional the details of the service were included, AstraZeneca provided copies of contracts with all of the participating health professionals. AstraZeneca submitted that all 13 of the health professionals had clearly documented in their service agreement that this was 'training' or 'rep training' as well as detailing their fee for participating in the one day training event. This clearly indicated their understanding of the training purpose at the event. To further ensure clarity of understanding by the health professionals, members of the training service provider team were also present to answer any questions from the health professionals to support completion of the service agreements on the day of the event. In addition, all the health professionals who participated in the event on 20 June also completed the briefing session with the training service provider team who made clear that this was a representative training event and also explained in detail their role on the day.

In relation to this point, AstraZeneca submitted that Clause 20.1 of the Code stated that the written contract must specify the nature of the services to be provided and payment details. This Code requirement was clearly addressed by the above process. In addition, the training service provider invitation used for this training event also provided detailed information of the service and event. It stated the following:

'Invitation to Training Event
I am writing from a company called The training service provider, a Pharmaceutical Outsourcing Sales, Medical & Marketing Services Company working on behalf of a leading pharmaceutical company.

We are holding an In Call Quality training event [in June] and are looking for GPs to attend'

AstraZeneca provided a copy of Appendix 1 of the service contract, and confirmed that this was an internal the training service provider document providing information on the legitimate needs for the services requested by the client.

Following a request for further information, AstraZeneca submitted that within each call cycle, the duration of each call was set to ensure sufficient time for each representative to conduct a full call whilst at the same time reflecting a realistic duration of such calls in the field, to ensure that the

medical representative/integrated healthcare specialist had a meaningful assessment. Thus the assessed call duration for this exercise was driven in part by, and consistent with, data contained in the AstraZeneca customer relationship management database on average call duration. This further supported the CDC objective of helping to replicate the 'real world' environment to better help meet the overarching training objective of the June CDC series. Therefore based on this, 15 minutes was determined as a sufficient duration for a GP representative to complete an assessed call. Similarly, 30 minutes was determined a more suitable call duration for an integrated healthcare specialist who worked in a hospital setting where often the discussions were more detailed and complex and thus required a longer duration. In addition, the training service provider also confirmed that such assessed call durations were normal practice across the pharmaceutical industry.

Three assessed calls for each representative was determined as critical for success of the June CDC series of events for the following reasons:

- The objective of the CDC series was to measure in an assessed environment the true level of skill and capability that each representative consistently demonstrated and applied in every call. Therefore, in contrast to a single call or two calls where a representative might get 'lucky', three calls were much more statistically robust and gave a much better indication of the true capability level of the representative.
- Compared with one or two calls, three also better supported representatives practising across multiple different environments eg different products/indications or with different customer groups. Therefore a series of three assessed calls was a broader test of ability than one or two assessed calls.
- To further reduce the impact of variability of scoring across assessors and observers as well as reduce the impact of a single weaker call due to 'nerves' or an event out with their control.

Therefore, in AstraZeneca's experience, three assessed calls provided a significantly more representative view of the performance of each representative including consistency and breadth than one or two calls would provide. As a result the outputs from this exercise resulted in more meaningful information upon which individual development plans could be developed.

When asked to comment on whether the number of health professionals taking part in the training events was reasonable in relation to achieving the training objective, AstraZeneca submitted that to understand the total number of health professionals involved in the project it was important to note that these events were conducted regionally and that this required a greater number of health professionals than would have been required for a smaller national event. The rationale for the regional approach was explained above. Other key considerations in terms of determining an appropriate number of health professionals were the number of assessments and the number of different specialities/environmental settings to be covered in the assessments, to ensure a good reflection of the responsibilities of each of the delegate types.

Therefore to help understand these numbers at a national level it was useful to consider the event in question. A total of 17 health professionals were chosen, 13 of whom participated as consultants. From the total of 17 health professionals scheduled for the event, there were eight GPs; four GPs who were scheduled to complete 39 x 30 minute call cycles and four who were scheduled to support preparations by 13 medical representatives for the assessed calls in the hot desk area.

In addition, from the 17 health professionals scheduled for the event, nine specialists were recruited (cardiologists, diabetologists, rheumatologists, respiratory physicians and payers) and they also split between the assessed calls and hot desk groups to support 12 x 50 minute call cycles for the integrated healthcare specialist group. The higher ratio for the number of specialists to representatives for the integrated healthcare specialist group reflected the fact that five different expert groups were recruited so that each integrated healthcare specialist was able to complete three different assessed calls with three different consultants relevant to the therapy area/setting for products which they would normally promote (cardiology, diabetology, respiratory medicine, rheumatology and payer). On the day of the meeting, three consultants allocated to the integrated healthcare specialist group did not attend which unfortunately resulted in two out of four integrated healthcare specialists having to do repeat assessed calls with the same consultant. Therefore for the event in question there was a total of 51 assessed calls for the 13 health professionals who participated.

Similar considerations applied to each of the other 10 CDC events and to further illustrate this AstraZeneca provided an additional breakdown of the numbers of health professionals at each event.

Therefore, overall a total of 304 representatives participated across the 11 events with a total of 910 assessed calls. This was supported by a total of 206 health professionals who facilitated both the assessed calls and hot desk area. Therefore, based on the above information, it was AstraZeneca's view that the number of health professionals who participated in the 11 CDC events was entirely proportionate to meeting the training requirements of these events.

PANEL RULING

The Panel noted that the complainant raised concerns about the invitation. The complainant had not attended the training. The Panel considered that

in order to determine whether the invitation was appropriate it had to determine first whether the training was appropriate. The Panel noted that the complainant was concerned that the invitation was not targeted to her for her specific expertise as she was not an expert in training sales representatives. The complainant had been asked to recruit colleagues to attend. In replying to the invitation the complainant stated that the events were sophisticated attempts to get doctors to listen to the same marketing information repeatedly and 'getting round the problem by paying doctors to become brainwashed by calling it rep training'.

The Panel noted that the assessment had been organized by the training service provider on behalf of AstraZeneca. The invitation at issue had been sent by an agency on behalf of the training service provider.

Neither AstraZeneca nor the training service provider had seen the invitation at issue. This was of serious concern to the Panel and in its view indicated a lack of control. The Panel noted AstraZeneca's comments on its relationship with the training service provider. In the Panel's view AstraZeneca was entirely responsible under the Code for the acts and/or omissions of the training service provider, and the two other agencies. If this were not so, companies would be able to circumvent the requirements of the Code. The Panel noted that there was no AstraZeneca document specifically briefing the training service provider in relation to the details of the training events. An AstraZeneca document setting out the ambition for the project in terms of upskilling the representatives shared with the training service provider was provided.

The invitation stated that the author was 'conducting a study with specialists and medical reps' and referred to 'research'. The Panel considered that the invitation to the complainant was not sufficiently clear that it was not a market research event but related to an assessment of the performance of the representatives. The invitation stated that it was 'a day long workshop, which includes running mock consultations with reps as well as doing some group and individual exercises'. In the Panel's view the invitation implied that the mock consultations were only part of the agenda as there would be group and individual exercises. The invitation did not state that it was a pharmaceutical company event. There was no indication of the nature of the client.

The Panel considered that the invitation to the complainant was due to her professional experience and not in relating to training sales representatives. In the Panel's view this was not unacceptable.

The Panel then turned its attention to the arrangements for the meeting in question.

The Panel noted that one of the slides describing the CDC referred to local events and local customers. The Panel accepted that the local conditions could be relevant to some aspects of representatives' calls and performance. The Panel noted that in 2010 the CDC training event had been run nationally, rather than on a regional basis. The Panel considered that it would be possible to adapt a national format whilst ensuring that local differences, such as differences between the devolved nations, were met. The Panel did not accept the company's submission on this point. The Panel was very concerned that the local nature of the events meant that it was highly likely that some of the health professionals participating in the training were those upon whom the same representatives would be calling on, or had previously called on, in a professional capacity. In the Panel's view it would have been preferable if the arrangements were such that no representative was assessed by a health professional or payer upon whom they were expected to call. AstraZeneca had not issued any guidance for representatives in this regard. Robust safeguards should be in place to ensure a clear separation between the training and subsequent contact given the local nature of the activity.

The Panel noted that each medical representative was to be assessed three times and was given 15 minutes for the assessed call. The Panel queried whether this was in line with what happened in the field but noted the company submission that the duration and number was not out of line with other companies' training arrangements, was much more statistically robust and gave a better indication of the true capability of the representative. The Panel had similar concerns with the time allocated to the integrated healthcare specialists assessed calls (30 minutes).

Clearly it was important to train representatives and to assess that training but the Panel had some concerns about the scale of the activity. Training all representatives was a legitimate aim but the Panel queried whether it was necessary for every representative to be assessed for 3 calls, particularly in relation to those calling upon GPs. It would have been possible to assess some of the representatives or to limit the number of calls and use that learning to better inform relevant staff. In this regard the Panel noted that in total 304 representatives participated in 11 events with 910 assessed calls involving 206 health professionals who facilitated both the assessed calls and the hot desk area. The Panel queried whether the number of health professionals/payers retained was consistent with Clause 20.1 which required that the number of consultants was not greater than the number reasonably necessary to achieve the identified need.

The Panel noted that according to the individual summary reports from the meeting in question in June 2011, nine of the 17 representatives had previously attended two similar events in January 2011 and in October 2010 where the same parameters were assessed. Two had attended one previous event and six had just attended the June

event. The Panel had some concerns about frequency of the events and the genuine need for further assessment as it appeared that nine representatives had already been assessed on the same parameters twice since October 2010.

The Panel queried the validity of AstraZeneca representatives undertaking repeat assessed calls with the same health professional/payer. The Panel was also concerned that the AstraZeneca sales team referred the names of health professionals to their manager for possible invitation by the training service provider to the event.

The use of a health professional on the 'hot desk' was of concern. Although it might be helpful to the representative the Panel was unsure whether this was an appropriate activity given that it was arranged on an 'as needed' basis. Attendance at the hot desk was not mandatory.

Representatives were encouraged to visit the hot desk. The Panel understood the difficulty in recruiting health professionals/payers and understood the need to ensure that the event ran if some health professionals/payers did not turn up on the day. However, it seemed that the roles were different and it was difficult to justify the payments being the same.

The Panel noted that the health professional/payer completed 6 questions following the interview. The questions did not mention the product and focused mostly on the health professional/payer's professional needs. There was no mention of marketing messages. They were asked whether they would act differently as a result of this conversation.

The observer (either the training service provider, member of staff, an external contractor or an AstraZeneca sales manager) completed one form for health professional calls and another for payer calls. The observer health professional form was divided into sections 'Open and identify/clarity needs', 'Engage customer in compelling proposition - skills', 'Engage customer in compelling proposition - knowledge', 'Close and agree joint and future action', 'Overall Impact' and 'Emotional Intelligence'. Comments on a key strength and a key development area and overall comments were also required.

The observer payer form was different in that it included a section at the end for the observer to interview the payer to identify a key strength and a key development area. In addition the payer was asked about how compelled they were to see the individual again and whether they would change their behavior as a result of seeing the individual.

The Panel noted that payers were offered a higher consultant fee at £700 than either the GP (£500) or the specialist (£600). These rates did not reflect the AstraZeneca maximum hourly rate which in turn specified a rate for a specialist and GP which was almost double that of a payer. The justification for the higher daily rate for payers was due to the difficulty in recruiting such people. The Panel noted that each of the four integrated healthcare specialists had to complete one payer call (each call cycle was 50 minutes in duration). All consultants were paid for a full day and free to leave when their services were no longer required. The event started at 8.30am and according to AstraZeneca's submission was finished by 3pm.

The email from the training service provider to a third party agency set out the details of payment for health professionals/payers for the meeting in question and another elsewhere. The email stated that GPs were to be paid £500, and 'if you get some that are grumbling then up it'. The facility to increase payment applied to all of the fees for health professionals/payers. The payments were referred to as incentives which the Panel considered was an unfortunate choice of word given that the fee was supposed to be payment for a service that fulfilled a legitimate need. The Panel did not have a comparable email from the training service provider to the agency who sent the invitation in question.

The Panel noted that the invitation from the training service provider referred to the aim of the event which was to provide feedback to medical representatives. This invitation also referred to complimentary lunch and refreshments. This did refer to the fact that the training service provider was working on behalf of 'a leading pharmaceutical company' but further details were not given. The reply form was not clear in that regard.

The Panel noted that participating health professionals and payers completed service agreement forms. These stated that the service was to assess representatives' training. The consultancy services approval form was not clear that the training service provider was working on behalf of a pharmaceutical company. The services to be provided were detailed on Appendix 2 which again did not mention that the training service provider was working on behalf of a pharmaceutical company.

Taking all the circumstances into account, the Panel did not consider that the event was a *bona fide* training event. The Panel was concerned about the scale of the activities and that representatives were being assessed by customers upon whom they might be expected to call, in the absence of safeguards. The Panel noted its concerns set out above and taking all of the circumstances into account considered that the training session was promotional. It was disguised in this regard and a breach of Clause 12.1 was ruled.

The Panel noted its concerns set out above. AstraZeneca had not established a robust distinction between the training in question and subsequent professional contact. The Panel noted its ruling above that the event was disguised promotion and considered that any payment to

attend was therefore in breach of Clause 18.1. A breach of Clause 18.1 was ruled.

The Panel recognised the need to use health professionals as consultants in the training of representatives, and that some of the information collected at the event in question could lead to professional development plans for the representatives participating. The Panel noted the criteria set out for the hiring of consultants in Clause 20.1. It considered that the criteria for selecting the complainant was related to the need for the service and ruled no breach of Clause 20.1 in this regard. Clause 20.1 also required that the compensation for providing the services must be reasonable and reflect the fair market value of the services provided. The Panel did not consider that the level of the payments for the payers and the hot desk together with the implication that all payments could be increased by the agency following adverse comment from those invited met that criterion. The Panel also noted its comment above that the event was not a *bona fide* training event. Clause 20.1 required that the hiring of a consultant to provide a relevant service must not be an inducement to prescribe, supply, administer, recommend buy or sell a medicine. The Panel noted its ruling above of a breach of Clause 18.1 in relation to the payment of honoraria for an event that was considered to be disguised promotion. The Panel considered that the arrangements thus failed to satisfy the requirements of Clause 20.1 and a breach of that clause was thus ruled.

The complainant had made a general allegation regarding Clause 20. The Panel did not consider that Clauses 20.2, 20.3 and 20.4 were relevant as they related to declaration of payment of fees. No breach of those clauses was ruled.

APPEAL BY ASTRAZENECA

AstraZeneca submitted that it was responsible for all of the activities carried out by third parties on its behalf and as such recognised the imperfect wording of the invitation. However, although the documentation could have been better, this did not in itself, lead to or support the conclusion that the health professionals were not hired as genuine consultants to AstraZeneca and that the event in itself was of poor quality and/or in breach of the Code. AstraZeneca submitted that the event was a *bona fide* training event and a key element of its sales force development programme and as such it refuted the Panel's ruling that this event was disguised promotion. As this was the foundation of its rulings, AstraZeneca appealed the Panel's rulings of breaches of Clauses 12.1, 18.1 and 20.1.

AstraZeneca explained that the training event at issue formed part of a larger AstraZeneca programme of training activities called Competitive Capabilities. The Competitive Capabilities programme started in 2010 with the overarching goal to up-skill the AstraZeneca sales force across multiple capabilities. The programme was currently AstraZeneca UK's single largest investment in developing its employees and to date had involved over 700 sales force members.

The programme consisted of multiple different initiatives and was focused on developing the capabilities of the sales force, including, for example, training on coaching and performance management for managers and in-call effectiveness and excellence in product knowledge for representatives. Through such interventions, AstraZeneca set out to better meet the needs of today's health professionals by helping its representatives add greater value to health professionals and the NHS through the quality of their interactions.

The programme had two key objectives:

- the objective assessment of the capabilities of representatives in an environment which recreated, as closely as possible, the reality they faced as part of their interactions with health professionals.
- the development of individual development plans that supported business, career and personal development.

The training day in June 2011 was a CDC event: a key component of the Competitive Capabilities programme. A CDC was a training event that directed and supported the up-skilling of representatives through the objective assessment of in-call performance, conducted in a safe training environment that also allowed them to both practice and learn key skills. In order to ensure the training environment was as close to reality as possible, health professionals, usually GPs or consultants, with the relevant therapy area/clinical expertise for the exercise, were engaged as consultants to participate in assessed calls. The use of consultants was vital to ensure that the capabilities of the representatives was evaluated objectively in an environment which recreated, as close to reality as possible, a representative/health professional interaction, whereby the consultant asked the types of questions typical of a normal call. It was not possible to achieve the same outcome using actors or by engaging in role-play with other representatives: this was why many pharmaceutical companies also used methods similar to AstraZeneca's in their training programmes and why there were at least six vendor companies in the UK supporting the pharmaceutical industry with such activities. Consistent with most *bona fide* training activities, the outputs from a CDC event were used to support individual development plans and to direct interventions specifically, and sometimes individually, designed to improve further the capability levels of the representatives.

In the CDC assessed calls, there was a delegate (representative), an assessor (health professional consultant) as well as an observer (AstraZeneca sales manager, the training service provider employee, or an external independent assessor).

AstraZeneca noted that UK law required pharmaceutical companies to train their representatives and to 'ensure that, in relation to any such product which medical sales representatives promoted, those medical sales representatives are given adequate training and have sufficient scientific knowledge to enable them to provide information which is as precise and as complete as possible about that product'. For AstraZeneca, CDC events were one of the key ways to meet that legal obligation, both in terms of providing training, and in assessing that such training had the required skills and capabilty impact.

Of fundamental relevance to this appeal, the Panel in its ruling stated that 'it had to determine whether the training was appropriate'. AstraZeneca also agreed with the Panel's view that the outcome of this case rested on the legitimacy (or otherwise) of the underlying training activity. If it could be demonstrated that this event was a legitimate training activity then AstraZeneca asserted that the Appeal Board must rule no breach of Clauses 12.1 and 18.1. In addition, AstraZeneca submitted that additional information provided below demonstrated that the requirements of Clause 20.1 had been addressed in full.

Invitation from third party agency

This was an email invitation for health professionals to participate in the CDC training event in June and sent a third party agency on behalf of the training service provider. On review of the invitation AstraZeneca acknowledged that the use of terms such as 'study' and 'research' was questionable, as such terms were classically associated with market research rather than training. However, although some of the language was unfortunate, AstraZeneca submitted that the recipient was in no doubt that this was an invitation for a training event and not for any other kind of activity. Indeed, the complainant referred to the activity as 'rep training', indicating that she understood to what activity the invite pertained. This understanding by the complainant would have been supported by the subject line of the invitation: 'Training Day research invitation' as well as other language and statements used in the body of the email such as 'running mock consultations with reps' and 'aim of the workshop is not only to aid in improving reps performance but also to gain feedback on what would make rep visitations more useful for health care professionals'. This language left the reader in no doubt that the email constituted an invitation for a consultant to support representative training activity.

AstraZeneca took full responsibility for all of the activities carried out by third parties on its behalf and as such recognised the questionable wording of the invitation. This was an issue that it recognised prior to, and independently of, this complaint, and it had recently rolled out a global initiative, which gave it the contractual power to further drive standards in all of the external interactions delivered by contracted third parties; it was now implementing additional controls and processes to ensure that either bespoke or template invitations to health professionals for similar training events, and other key documentation, were in line with AstraZeneca's own standards and were, where required, formally reviewed prior to use.

The CDC event was a *bona fide* training event; the invitation (albeit imperfectly worded) testified to this, as did the fact that the type of activity described in the invitation was correctly understood by the complainant.

AstraZeneca submtted that a key component of the original complaint was that the recipient stated that they did not have the required expertise to be a suitable consultant to the CDC training event and therefore should not have been invited. However, the Panel dismissed this complaint, concluding that the complainant's professional expertise alone was sufficient for her to be invited to participate in this event. Relevant professional expertise was the key selection criteria used for recruitment to these events.

Working relationship between AstraZeneca and The training service provider

The Panel stated that 'there was no AstraZeneca document specifically briefing the training service provider in relation to the details of the training events'. However, the business relationship between AstraZeneca and the training service provider was not a 'contracting-out' relationship, but a 'preferred partner' relationship. Thus AstraZeneca contracted with the training service provider to deliver the CDC event series in partnership. The nature and content of the contract and briefings reflected this 'design and deliver together' approach. This did not indicate, as decided by the Panel that AstraZeneca had devolved all responsibility for the training event to a third party. In fact, this working practice resulted in AstraZeneca playing a very hands-on role in the development and implementation of the resultant activities, and required AstraZeneca staff to stay in control of the overall programme. This practice did not require detailed briefing documents, as all details were worked out together in meetings and through informal communications.

AstraZeneca and the training service provider had worked very closely on a number of projects and the training service provider was seen as a preferred partner by AstraZeneca for conducting these types of training events eg last year the training service provider, worked in partnership with AstraZeneca to complete a successful national training event which involved health professionals as part of the Competitive Capabilities programme. AstraZeneca had continued this close working relationship with the June CDC series of events which were designed, developed and implemented over a two month period through a close working

relationship between the two organisations built on excellent and frequent communication including weekly meetings. AstraZeneca believed that this working relationship had been central to its success in conducting the June CDC events.

In addition, this project was further supported with the agreement 'SFE Standard Terms & Conditions MR/IHS and FLSM CDC AstraZeneca'. Much of the initial discussions on this project developed and evolved from its shared experiences in conducting a national event in 2010 as well as through an initial presentation from the training service provider to AstraZeneca at the design phase, outlining potential options for this CDC project. A further document shared with the training service provider also set out the ambition for this project in terms of up-skilling its representatives and integrated healthcare specialists across a series of 11 CDC events. Further to this, AstraZeneca had also included one of the project estimates for the regional CDC events from the training service provider as well as an email summarizing one of the AstraZeneca briefing meetings.

This close working relationship between the two companies through both frequent and informal briefings, underpinned with additional documents above, had enabled the two organizations to work closely and quickly together to complete the June CDC training events; involving 910 assessed calls and 304 representatives. To have successfully completed this project over such a short period of time was testimony to the success of this working model.

Considerations relating to clear separation of non-promotional training and promotional activities

AstraZeneca noted the Panel's comments on the regional approach adopted for the June CDC series of events. During the design phase for the June CDC project it was decided that there would be 11 regional training events spread across the four UK nations. This was following feedback and learnings from the national CDC event series which took place in 2010; the key considerations for the regional CDC series were:

- Regional events supported the assessment of in-call performance and associated capabilities in a more 'realistic' environment than would take place at a national event. AstraZeneca noted that the Panel generally agreed with this position in that it stated 'local conditions could be relevant to some aspects of representatives' calls and performance'. At a national event last year there were situations where representatives had to complete assessed calls with health professional who worked in a very different health setting eg an English representative was allocated to a health professional from one of the devolved nations who had different health priorities which the representative would not be expected to know. However, all local health economies varied in their priorities and in the formulation of their formularies and treatment protocols, resulting in what could be significant differences in practice and approach. Therefore, the regional approach was a sensible compromise, which enabled a more realistic setting for assessed calls to take place supporting the overarching training objective – to evaluate objectively the capabilities of the representatives in an environment which recreated, as closely as possible, the reality they faced as part of their interactions with health professionals.

- Feedback from a national event showed that regional events could often be a less stressful environment for many representatives allowing them to complete their assessed calls in a manner more likely to be similar to the way in which they would conduct their normal calls.

- Logistically, regional events were more efficient in that they reduced the amount of time health professionals spend away from clinics and patient care and the amount of time a representative was absent from their territory and home.

AstraZeneca acknowledged the Panel's concerns that the regional nature of the event meant that there was a chance that some of the health professional consultants employed could be those upon whom the participating representatives would normally call upon or had previously called upon in a professional capacity. In AstraZeneca's view this non-promotional training event in its set-up and implementation should be, and was conducted entirely separately from other types of representative activities. Importantly, the allocation of health professionals to a particular assessed call in the schedule with a particular representative was conducted by the training service provider without knowledge of AstraZeneca's sales territories or customer contacts; at no point was such information shared with the training service provider for the purpose of the CDC series.

AstraZeneca also noted the Panel's suggestion that it would have been possible to adapt a national format whilst ensuring local differences, such as differences between devolved nations, were met. Whilst AstraZeneca recognized that designing and implementing a national programme, taking into account local considerations, would be possible to some degree, the overarching training experience and the ability to meet the training objectives for a national event would not have been addressed in the way that was possible with a regional approach, for the reasons stated above.

AstraZeneca noted the Panel's comment that 'robust safeguards should be in place to ensure a clear separation between the training and subsequent contact [with health professionals] given the local nature of the activity'. In contrast to the Panel's comments, by contracting with the training service provider, AstraZeneca had ensured appropriate safeguards in terms of separation between the

training event and other representative activities. In support of this, AstraZeneca confirmed that it was not responsible for the recruitment of health professionals to the event, and that it provided no briefing or direction in terms of using AstraZeneca-generated contact lists as part of the recruitment process.

AstraZeneca also noted that there was no specific Code requirement for briefing documents to be in place for how representatives should conduct themselves with health professionals following their engagement as consultants to a company, and that the Code did not prevent representatives directly engaging one of their customer health professionals as a consultant on a fee for service basis, for example as a speaker at a local meeting. Importantly, AstraZeneca was not aware of any complaints or issues relating to representatives inappropriately using any CDC training event to gain subsequent contact with a health professional or indeed to inappropriately influence their prescribing behaviour. However, in recognition of the Panel's comments, AstraZeneca would produce a specific briefing document for representatives involved in future similar training events, to ensure absolute clarity on their obligations under the Code relating to any subsequent contact with health professionals who might have participated in such events.

Considerations on scale

AstraZeneca noted that the Panel had been concerned about the scale of the activity both in terms of the duration and frequency of assessed calls completed for the June CDC series of events. In order to respond to this point it was helpful to consider the development of the call cycle. For the June CDC, the duration for a full call cycle with a representative was 30 minutes and 50 minutes for an integrated healthcare specialist.

Within each call cycle, the duration of each assessed call was set to ensure sufficient time to conduct a full call whilst at the same time reflecting the real-life duration of such calls in the field, to ensure that the medical representative/integrated healthcare specialist had a full and meaningful assessment. Thus the assessed call duration for this exercise was driven in part by, and consistent with, data contained in the AstraZeneca customer relationship management database on average call duration. This further supported the CDC objective of helping to replicate the 'real world' environment to better help meet the overarching training objectives of the events. Thus 15 minutes was determined as a sufficient duration for a GP representative to complete an assessed call and 30 minutes was determined a more suitable call duration for an integrated healthcare specialist who worked in a hospital setting where discussions were often more detailed and complex. In addition, to ensure a robust and fair assessment it was important that calls were long enough to allow the representatives to demonstrate their full skill and capability. Nevertheless 15 and 30 minutes were considered as maximum call durations and in many cases the assessed calls were significantly shorter. In addition, the training service provider also confirmed that on review of previous similar sales force effectiveness events that these call durations were consistent with those conducted by other pharmaceutical companies.

In terms of absolute number of assessed calls to be completed per representative, three was determined as critical for the success of the June CDC events because:

- The objective of the CDC series was to measure in an assessed environment the true level of skill and capability that each representative consistently demonstrated and applied in every call. Therefore, in contrast to one or two calls where a representative might get 'lucky', the use of three assessed calls was more methodologically robust and gave a better indication of the representative's capability.

- Compared with one or two calls, three also allowed assessment of representatives practicing across multiple different environments eg different products/indications or with different customer groups. Therefore three assessed calls was a broader test of ability than one or two assessed calls.

- Three calls further reduced the impact of variability of scoring across health professional assessors and observers and reduced the impact of a single weaker call due to 'nerves' or an event outwith the representative's control.

The training service provider had also confirmed that three assessed calls was considered by most of its pharmaceutical company clients as an appropriate balance between speed and cost on the one hand and precision and reliability on the other, although some clients had used two assessed calls per representative per event and others four assessed calls.

The importance of conducting three assessed calls was further illustrated by an audit of the June CDC series. The assessment scoring methodology had been consistently employed based on the criteria as follows:

- Score 1 = Poorly demonstrated or not demonstrated at all – clear area of weakness
- Score 2 = Some evidence but opportunity for improvement
- Score 3 = Good demonstration of skill (meets management ambition)
- Score 4 = Excellent demonstration of skill – a clear area of strength

The key mean threshold score for AstraZeneca was set at 2.5 and the target ambition level for all representatives was greater than 3. The implications of this on AstraZeneca's representative scores (for

illustration purposes) was that the importance could be seen of conducting three calls to ensure adequate levels of sensitivity and specificity. In this sample, detailed in the table below, 303 representatives each completed three assessed calls. The outcome was very different if their overall score was based only on their first assessed call compared to all three assessed calls.

AstraZeneca provided a more detailed analysis which it submitted demonstrated the importance of conducting three assessed calls per representative to improve the sensitivity and specificity of the assessment process and also further supported AstraZeneca's approach to conducting three assessed calls per representative per event.

In summary, three assessed calls was an appropriate number and provided a significantly more robust view of each representative's performance, including consistency and breadth, than one or two calls would provide. As a result the outputs from these events resulted in more meaningful information upon which individual development plans had been developed.

AstraZeneca was concerned that the Panel's statement that 'it would have been possible to assess some of the representatives or to limit the number of calls and use that learning to better inform relevant staff' suggested a fundamental lack of understanding by the Panel of the legitimate training objectives that underpinned the CDC series. To extrapolate learning from a few assessed calls conducted by a few representatives to the entire sales force did not support the development of individual development plans, which was a cornerstone of this programme. AstraZeneca contended that the Panel's apparent lack of understanding must put into further question its overall ruling in this case which it stated 'took all the circumstances into account'.

AstraZeneca also noted that the CDC was an integral and fundamental tool in the performance management and career development of its employees and had also recently been one of the selection criteria used in a redundancy exercise. From an employment law perspective, therefore, and having regard in particular to the provisions of the Equality Act 2010, AstraZeneca could not treat its employees differently regarding the CDC training. AstraZeneca could allow some employees access to the CDC but others not, thereby exposing it to the risk of discrimination claims (from either group of employees) on the basis that it did (or did not) consider it to be a positive step to undergo the CDC training; equally, representatives might consider it unfair and/or discriminatory if they were subjected to different levels of CDC training. In this respect, therefore, if the Appeal Board acknowledged that the CDC was an appropriate training vehicle, it should also be acknowledged that the CDC training itself must be applied consistently to every representative.

AstraZeneca also noted that the Panel queried whether the number of health professionals retained was consistent with Clause 20.1, which required that the number of consultants was not greater than the number reasonably necessary to achieve the identified need. To understand the total number of health professionals involved in this project it was important to note that these events were conducted regionally and that this required proportionately more health professionals than would have been required for a similar national event. The rationale for the regional approach was explained above. In addition, the other key considerations for determining the required number of health professionals were the number of assessments and the number of different specialities/environmental settings to be covered.

AstraZeneca did not brief the training service provider on the required number of health professionals for the event. Rather, AstraZeneca determined the number of representatives to be assessed and the number of assessed calls per representative by therapy area setting/environment and on that basis the training service provider determined the number of health professionals needed to complete the event. To understand these numbers at a national level it was useful at this point to consider the event at issue. For this event 17 health professionals were invited and accepted; 13 of whom participated as consultants. From the 17 health professionals scheduled for the event, there were 8 GPs; 4 GPs were scheduled to complete 39 x 30 minute call cycles and 4 were scheduled to support preparations by the 13 medical representatives for the assessed calls in the hot desk area described further below.

In addition, from the 17 health professionals scheduled for the event, 9 specialists were recruited (cardiologists, diabetologists, rheumatologist, respiratory physicians and payers) and they were also split between the assessed calls and hot desk groups (described further below) to support 12 x 50 minute call cycles for the integrated healthcare specialist group. The higher ratio for the number of specialists to representatives for the integrated healthcare specialist group reflected the fact that five different expert groups were recruited so that each integrated healthcare specialist could complete three different assessed calls with three different consultants relevant to the different therapy areas/settings in which they would normally promote; cardiology, diabetology, respiratory medicine, rheumatology and payer. On the day of the event, three consultants allocated to the integrated healthcare specialist group did not attend and so two out of four integrated healthcare specialists had to do repeat assessed calls with the same consultant.

Similar considerations applied to each of the other 10 CDC events and to further illustrate this AstraZeneca provided an additional breakdown of the number of health professionals that participated at each event.

Therefore, overall 304 representatives participated across the 11 events with 910 assessed calls. This was supported by 206 health professionals who facilitated both the assessed calls and hot desk area. Based on the above, AstraZeneca considered that the number of participating health professionals was proportionate to meeting the training objective of these events.

AstraZeneca noted the Panel's comments about the fact that representatives had participated in multiple CDC events. There was a clear and legitimate rationale for why representatives participated in one or more training events involving health professional assessors. The maximum number of CDC events completed by each representative as part of the Competitive Capabilities programme to date was two. These two CDC events were conducted in October 2010 (national) and June 2011 (regional). A further in-call validation event for representatives involving health professionals took place in January 2011 which was a national launch validation exercise for all representatives before releasing them to promote two new launch products. AstraZeneca noted that the summary report forms submitted to the Panel incorrectly referred to the January 2011 event as a 'CDC' event; launch validations of this type were conducted at the time of all product launches and were not part of the CDC series. However, the additional information collected at the January launch validation event was included in these reports as a further source of information to help representatives improve their capabilities. AstraZeneca noted that the Competitive Capabilities programme required annual assessment of capabilities to track performance, offer development feedback and maintain momentum behind continuous improvement ambition, and so the CDC events were planned to be conducted annually; the next similar CDC series for this representative cohort would be in 2012.

AstraZeneca submitted that the effectiveness of the CDC approach and of the methodology employed could be assessed by audit. The audits employed a different methodology to that employed in the CDC series in that representative effectiveness was measured in a real call by an independent assessor and the results reported as aggregated rather than at the individual level. This enabled AstraZeneca to assess the overall selling skills of its representatives and compare the results against an overall industry benchmark. AstraZeneca submitted that the CDC training programme had resulted in sustained and progressive objective improvements in the sales force over time thus demonstrating the effectiveness of the programme. After the June 2011 CDC series there was a 63% improvement compared with the average audit score prior to the first CDC event.

Finally, AstraZeneca noted that the Panel queried the validity of AstraZeneca representatives undertaking repeat assessed calls with the same health professional. These events were specifically designed to try to ensure that each representative should be able to complete three separate calls with three different consultants, but due to non-attendance by health professionals on the day of the meeting, this was not possible and two of the four integrated healthcare specialists had to have assessed calls with a consultant that they had previously been assessed by that day. Thus, for logistical reasons, only 2 out of 17 representatives conducted two calls on the same health professional which did not invalidate the legitimate training activity which this event constituted.

Referral of names of health professionals by AstraZeneca sales managers

AstraZeneca noted the Panel's concerns that its sales team put forward names of health professionals for possible invitation by the training service provider to the event at issue. In the final weeks before the event, the training service provider still needed to recruit additional specialists for the event and so the business manager for the area offered to help and asked three of his team to provide a list of potential suitable health professionals. This instruction was given by telephone and explained that certain categories of specialists were required for the event. Following this, the names of 8 respiratory physicians and 11 payers were sent to the business manager who in turn forwarded them to the training service provider for evaluation as to suitability for recruitment. Of the final 17 health professionals who were recruited, only two were sourced in this fashion. The representatives were not instructed to identify names of potential health professionals as an inducement to prescribe, supply, administer, recommend, buy or sell any medicine. This course of action was undertaken solely to address the recruitment challenges faced by the training service provider in the run-up to the event at issue.

The hot desk

AstraZeneca noted that the Panel was unsure as to whether the hot desk was an appropriate activity given that it was arranged on an 'as needed' basis. As stated previously, this was a key role as the hot desk consultant helped representatives or integrated healthcare specialists prepare for assessed calls and could also cover for non-attendance of health professionals scheduled to participate by being re-assigned as health professional-assessors.

It was clear from the feedback that hot desk health professionals were seen as an invaluable resource by the representatives in helping them to prepare for assessed calls. Examples of discussions which took place between the 'hot desk' consultants and representatives included topics such as:

- Information which health professionals found useful to be communicated in calls.
- Feedback on challenges that a representative might have encountered in one call so that they

could better prepare for the next.
- Practice sections of the call such as the call opening at the start of an assessment.
- Understanding of current events in the NHS to help ensure that assessed calls were more aligned with a health professional's agenda.

As stated previously, a key role of the hot desk health professional was to be an additional and optional training and information resource, for those representatives who wanted to use it to help them prepare for subsequent assessed calls. Representative interactions with the hot desk health professionals were not assessed. On the morning of the event as part of the sales representative briefing, the purpose of the hot desk health professionals was made clear.

In most cases, health professionals were recruited to provide a service to support the delivery of the training event and not specifically recruited to either the assessor or hot desk roles. The training service provider had confirmed that although health professionals were provisionally allocated to the two different roles before the meeting, final allocation was only on the morning of the event, as experience had shown that attendance/non-attendance on the day was variable and could not be pre-judged.

The Panel was also concerned that health professionals were paid according to their professional expertise and not by what they did on the day ie hot desk or call assessor. In AstraZeneca's view the appropriate payment was made on the basis of professional experience and contracted time and was not based on the specific activities conducted on the day. This was no different from many other consultancy arrangements.

Payment levels

The Panel noted that payers were offered a higher consultant fee at £700 then either the GP (£500) or the specialist (£600) and that these rates did not reflect the AstraZeneca maximum hourly rate. Payment rates used for the recruitment of all 17 health professionals were determined by the training service provider and were based on one-day's work at this type of training event.

The rates, used were based on years of experience in using consultants at events such as sales force effectiveness meetings. The training service provider determined these rates through referencing the rates used in other contexts such as for speaker events, clinical research and private health delivery. Based on its experience across the industry, these were consistent and competitive when compared with those offered by other leading pharmaceutical companies in the UK. AstraZeneca confirmed that these fair market values were similar to those included in a separate proposal for the same project from another independent provider of sales force effectiveness solutions. AstraZeneca submitted that although its internal recommended consultant fair market value rates did not have a specific category for this type of training event. Whilst AstraZeneca recognized that its fair market value rates indicated a lower hourly rate for payers, lower than both that indicated for GPs and consultants, it was important to note that the total paid to payers by the training service provider was in line with AstraZeneca fair market values, and therefore not considered excessive.

Furthermore, there were modest differentials between the fees determined for GPs, specialists and payers. This was based on fair market value rates for recruitment to these types of activities. The training service provider confirmed that it was more difficult to recruit payers than other health professionals to such events hence the levels set by the training service provider and determined as appropriate for this project. Interestingly, The training service provider was able to negotiate lower fees with GPs and consultants than was AstraZeneca, hence the apparent discrepancy in fees commented upon by the Panel, not that payers received an excessive fee, as suggested by the Panel. Indeed, this was seen by the fact that on an hourly basis, the training service provider rates were lower than the AstraZeneca fair market rates for all the assessor types with the exception of the payers (where they were essentially the same).

As stated above health professionals were paid the same rate irrespective of whether they were an assessor or a hot desk health professional. This rate was based on their professional background and therefore the experience they brought to the day, and the time they were expected to dedicate to this activity – a full day.

AstraZeneca also noted that the Panel was concerned about the content of the email from the training service provider to a third party agency, which referred to 'if you get some that are grumbling then up it'. AstraZeneca confirmed that although the email was unfortunately worded, in no cases did payment levels deviate from those detailed in the email between the training service provider and a third party agency or from the values defined in the AstraZeneca fair market values table. However, AstraZeneca acknowledged that the use of such language was unfortunate and it had informed the training service provider on this point. Of concern to AstraZeneca, the Panel had inferred that this email therefore indicated that the facility to increase payments, without limits, applied to all of the fees for health professionals, and as 'incentives' to attend rather than as fair payment for the service rendered. AstraZeneca had not stated this anywhere and was unclear on what basis the Panel had drawn such a conclusion. To further reassure the Appeal Board, AstraZeneca confirmed that across all 206 health professionals for the June CDC series, the maximum payment amount was: GP £500, specialist £600 and payer £700. As a further demonstration of this consistency in application of agreed maximum fees, the training service provider had informed AstraZeneca that one GP asked for a

payment of £600 which was declined.

With reference to the Panel's specific concerns about the use of the term 'incentive' used in an internal email between the training service provider to the third party agency, AstraZeneca highlighted that it was clear to the reader that incentive would be interpreted by the recipient as reference to the payment rate for a service. Nevertheless, AstraZeneca recognised that incentive was an unfortunate choice of word to describe payments of this type and therefore it had provided feedback to the training service provider on this point. The word incentive in this internal email would be interpreted by the recipient to refer to payment for a legitimate service.

However, and without prejudice, AstraZeneca had identified prior to, and independently of this complaint, that third party documentation was not always to the standard it required, and it had recently rolled out a global initiative which gave it the contractual power to further drive standards in all of the external interactions delivered by contracted third parties; AstraZeneca was now implementing additional controls and processes to ensure that key documentation was in line with AstraZeneca's standards and were, where required, formally reviewed prior to use.

Standard invitation and service agreement form from the training service provider to heath professionals

The Panel noted in its ruling that the standard the training service provider invitation explained that the aim of the event was to provide feedback to representatives. In addition it also stated that the training service provider was working on behalf of a 'leading pharmaceutical company' and the Panel stated 'that the reply form was not clear in this regard'. AstraZeneca submitted that this reply form made clear that the invitation was for a representative training event and set out to 'provide feedback to medical representatives on their interpersonal, presentation and selling skilling following a number of face to face calls' which made very clear the training intent. As there was no Code requirement for the name of the pharmaceutical company to be disclosed on this standard invitation, AstraZeneca disagreed with the Panel in this regard; this observation by the Panel had no basis on determining whether or not this activity would be considered a *bona fide* training activity.

AstraZeneca noted the Panel's comments on the service agreement and pointed out that 12 out of 13 health professionals who completed service agreement forms referred to AstraZeneca in the event field which showed that they were clear that this was an AstraZeneca event. Consistent with this interpretation, the training service provider had also confirmed that in the briefing event on the 20 June, AstraZeneca's involvement was made clear to all participating health professionals. AstraZeneca noted that it was not a Code requirement that such service agreements must include reference to the relevant pharmaceutical company. Nevertheless, AstraZeneca had provided the Panel's feedback on this point to the training service provider and as a result the training service provider had updated its agreements to include an entry for the name of the pharmaceutical company who had commissioned the training event to be conducted by the training service provider.

Assessment criteria and follow-up

AstraZeneca noted that the Panel described the detailed assessment forms used in the training exercise. Related to this, it was important that the Appeal Board understood the thorough assessments completed for every call conducted by both observers and the health professional following assessed calls. Through such a process, detailed individualized information relating to the performance of each representative across each of their calls was generated. For each call the observer completed an in-call effectiveness evaluation form which assessed the sales representative's performance across multiple areas as detailed in the response above.

AstraZeneca submitted that on the day of each event the representative was given photocopies of the completed assessment forms for all three assessed calls and an overall summary form containing the averaged scores from all their calls completed on the day. Following the event, individualized reports summarising their performance compared to previous CDC performance were produced. These had been sent to all the delegates to support them updating their individualized development plans. Such a strong focus on feedback and rigorous evaluation in this series of events was consistent with a high quality training intervention.

Over the summer these materials were used to support discussions between manager and representative across the UK to underpin development of refined development plans which were maintained in the AstraZeneca internal 'MyCoach' application as individualised development summaries (screenshots of the online tool which also has the relevant scores for each of the assessed calls in June 2011 uploaded for all 304 representatives were provided). The consequent 'development' contracts could be tracked and reviewed at subsequent field visits with further interventions implemented as required. Furthermore, the robustness of these assessments was also evidenced by the fact that elements of the CDC results were also used as one of the selection criteria in an AstraZeneca redundancy exercise. Therefore, it was important for the Appeal Board to understand the assessment and follow-up process so that it could be left in no doubt that this was a legitimate training activity.

In conclusion, AstraZeneca asked the Appeal Board to take an objective view of the overall activity,

taking into account all of the circumstances, and see it as a *bona fide* training event which incorporated extensive follow-up and individual development planning. AstraZeneca acknowledged that some amendments to this type of programme had been/would be incorporated, but this did not invalidate the fact that this was an industry leading training event, in intent, nature and delivery. AstraZeneca submitted that it had clearly demonstrated the rationale and rigor in the design and implementation of this event, that the scale was proportionate for the overarching objective of a training programme involving 304 representatives at 11 regional events and that the intervention had resulted in tangible improvements in measures of overall sales force effectiveness. If the Appeal Board agreed that this was *bona fide* legitimate training event, then it must also agree that such an activity was not promotional, either by design or effect. On this non-promotional training platform there could be no disguised promotion, and therefore no breach of Clause 12.1. Similarly as this was a *bona fide* training event and was in no way disguised promotion, AstraZeneca submitted that the Panel's ruling of a breach of Clause 18.1, relating to payment to attend, was not valid.

In relation to Clause 20.1, the Panel had already accepted that valid criteria were adopted for the selection of health professionals for the event (in terms of relevant expertise), and this was based on the need for the training service. Accordingly, the Panel had ruled no breach of the Code in relation to a key component of the original complaint. However, AstraZeneca did not agree with the Panel's ruling of breach of Clause 20.1 in respect of other aspects of the arrangement:

- The maximum payments to health professionals were as set out above and were in line with, or were less than, current AstraZeneca fair market value rates. The email from the training service provider to a third party agency which indicated a flexibility in payment levels which was not implemented and not in keeping with the actual payments made.

- Level of payment for different health professional types was in line with, or less than, current AstraZeneca fair market value rates, and consistent with the approach to determining fair market values; relevant expertise and time contracted. On this basis both hot desk health professionals and assessor health professionals were paid the same rate.

- As AstraZeneca considered that this was a *bona fide* training event and needed to be considered as such, the hiring of consultants was not an 'inducement to prescribe' as stated by the Panel.

AstraZeneca hoped that the above had clearly demonstrated that the event in question was *bona fide* training supported by the appropriate use of consultants.

COMMENTS FROM THE COMPLAINANT

The complainant stated that she had misunderstood her role in the complaint process, after the initial complaint. The process was very user unfriendly for an individual. It seemed more suited to pharmaceutical companies with extensive resources and legal departments. Perhaps on receipt of a complaint from an individual who would usually be making a complaint for the first time, the Authority might outline the process for the complainant, stating clearly and succinctly the subsequent steps in the process, further roles and responsibilities of the complainant, the appeals procedures, for the complainant and for the company complained about, and the possible outcomes and consequences for the pharmaceutical company if the complaint was upheld.

The complainant alleged that she had been unable to find in the extensive paperwork any mention of the specific products which were being discussed in the 'training' with the specialists recruited (diabetologists, respiratory physician, rheumatologist cardiologists). Surely knowledge of the actual content of the presentations to the clinicians was central to whether or not this was, as the complainant contended, disguised marketing? Why specify the specialities, if this was a generic training programme? The complainant, however, noted in the paperwork from AstraZeneca an analysis of a GP participant's prescribing patterns in relation to AstraZeneca's brands, which would seem to support the complainant's assertion that this event was primarily for marketing and not training.

The complainant strongly agreed with the Panel that if an individual pharmaceutical company representative had previously attended similar events within the last year, they had already been 'trained' and that attendance at further such events must be for other reasons, such as enhanced contact with local specialists, in promotion of the company's products.

APPEAL BOARD RULING

The Appeal Board considered that the use of health professionals in the training of pharmaceutical company personnel was a legitimate activity, as referred to in Clause 20.1. The question to be considered in this case was whether any promotion as a consequence of this training was necessary as part of the training, proportionate to the training element of the activity, and transparent. The first element to be considered was whether the activity was disguised promotion.

The Appeal Board noted AstraZeneca's submission that the training service provider had contracted a third party agency which had emailed the invitation to the complainant. The email was titled 'Training Day Research invitation'. It stated that the author was 'conducting a study with specialists and medical reps' and that the 'research' would involve 'mock consultations with reps as well as doing

some group and individual exercises'. The invitation stated that there would be a £600 payment. The Appeal Board considered that the invitation to the complainant was poorly written. It could imply that the recipient was being invited to a market research event for which they would be paid. The fact that the recipient was being invited to help train and assess the performance of representatives was not clear.

The Appeal Board noted that in 2011, 11 regional CDC events had used 206 health professionals to train 304 representatives. Clause 20.1 referred to the use of health professionals and appropriate administrative staff as consultants and advisors, provided that, *inter alia*, the number of consultants retained was not greater than the number reasonably necessary to achieve the identified need.

The Appeal Board noted AstraZeneca's submission that it had not decided on the numbers or individual identities of health professionals used, it had provided the training service provider with its training needs in terms of number of representatives and number of assessed calls required by therapy area setting/environment. The training service provider had then decided on the number of health professionals required and recruited them from lists that it held. The Appeal Board noted from AstraZeneca's representatives at the appeal that geographical factors affecting the required number of health professionals needed did not just relate to the devolved nations, but to different specialisms in a number of regionally distinct health economies. In addition regionally held events had increased the overall number of health professionals needed. The Appeal Board noted AstraZeneca's submission that three assessed calls were necessary to provide a fair assessment.

The Appeal Board noted AstraZeneca's submission that health professionals were briefed by the training service provider on the morning of the meeting and told that this was an AstraZeneca event. AstraZeneca's representatives at the appeal submitted that it was made clear that the objective of the day was assessment and training.

The Appeal Board noted from AstraZeneca's representatives at the appeal that the service agreement contracts were completed on the day of the event by the health professionals. Health professionals also completed a profile form which required them to state their clinical area of interest, current prescribing habits and 'AstraZeneca Brand Awareness' (none, low, moderate or high) for five of AstraZeneca's medicines. These forms were then copied to each representative to enable them to prepare a profile of the health professionals they were about to call on. The Appeal Board noted from AstraZeneca's representatives at the appeal that it was necessary for representatives to be judged on how they detailed the medicines that they normally promoted so that assessed calls were as close as possible to 'real world' calls in the field. The Appeal Board noted AstraZeneca's submission that added pressure for those being assessed was that the outcomes from the CDC assessments might be used in a redundancy process to remodel the sales force.

The Appeal Board noted AstraZeneca's submission that although the assessment could last either 15 minutes (representatives) or 30 minutes (integrated healthcare specialists), these were the maximum times allowed and calls could be shorter. AstraZeneca had submitted that the maximum call lengths were appropriate and reflected actual call times in the field.

The Appeal Board noted AstraZeneca's submission that because of difficulties in recruitment, it had given the training service provider the names of 19 health professionals to approach to participate in the CDC event. The training service provider had handled the recruitment and two of the 19 attended the subsequent CDC. At that meeting two representatives had been seen twice by the same health professional as three health professionals had unexpectedly failed to attend.

The Appeal Board considered that an unavoidable consequence of the training event would be the promotion of AstraZeneca's products but that the consultants' attention would be focused on providing information about the representative's performance, not on receiving promotional messages. The Appeal Board noted that AstraZeneca's representatives at the appeal submitted that the company had not monitored any subsequent changes in the prescribing habits of the participating health professionals.

The Appeal Board noted that the email from the training service provider to a third party agency set out the payment details for health professionals/payers for two of the meetings. The email stated that GPs were to be paid £500, and 'if you get some that are grumbling then up it'. The facility to increase payment applied to all of the fees for health professionals/payers. The Appeal Board noted that AstraZeneca acknowledged that the wording in the email was unfortunate, but the company stated that in fact none of the health professionals used in the CDC events were paid more than the maximum rates stated (£500 for GP; £600 for specialist and £700 for payer) and that these amounts were fair market value rates determined by the training service provider.

The Appeal Board noted AstraZeneca's submission that events held in January 2011 were not CDC but separate training for a new product launch. The CDC was an annual event.

The Appeal Board noted from AstraZeneca that the purpose of the CDC was to up- skill its representatives to meet the requirements of the NHS. Prior to the CDC series of assessment and training AstraZeneca submitted that the performance of its representatives fell below the industry benchmark. Since completing two years of CDC events its sales force performance

exceeded the industry benchmark.

Taking all the circumstances into account, the Appeal Board considered that on balance the event was a *bona fide* training event. Although the Appeal Board was concerned about the poor wording in the emailed invitation, it did not consider that the CDC training meeting was disguised promotion. The Appeal Board ruled no breach of Clause 12.1. The appeal on this point was successful.

The Appeal Board noted its ruling above that the event was not disguised promotion; the payment to attend was a genuine consultancy fee and so was not in breach of Clause 18.1. No breach of that clause was ruled. The appeal on this point was successful.

The Appeal Board noted the comments above about the complexity of the meeting and the requirement for a large number of health professionals and it considered that on balance the arrangements were acceptable and no breach of Clause 20.1 was ruled. The appeal on this point was successful.

Complaint received **16 June 2011**

Case completed **12 October 2011**