NUMBER 75 February 2012

CODE OF PRACTICE REVIEW

PMCPA Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the ABPI Code of Practice for the Pharmaceutical Industry independently of the Association itself.

FEWER COMPLAINTS IN 2011 THAN IN 2010, BUT MORE CASES

In 2011 the PMCPA received 84 complaints as compared with 86 in 2010. There were 92 complaints in 2009, 112 complaints in 2008, 127 complaints in 2007 and 134 complaints in 2006.

There were 84 cases to be considered in 2011, as compared with 78 in 2010. The number of cases usually differs from the number of complaints because some complaints involve more than one company and others do not become cases at all, often because they do not show that there may have been a breach of the Code.

The number of complaints from health professionals in 2011 (30) was more than the number from pharmaceutical companies (both members and non-members of the ABPI) (22). In addition there were six complaints from anonymous health professionals. Complaints made by pharmaceutical companies are generally more complex than those from outside the industry, usually raising a number of issues.

Three complaints were made by members of the public, two from journalists and one from a publisher.

There were thirteen anonymous complaints in addition to the six from anonymous health professionals.

The remaining seven complaints were nominally made by the Director and arose from voluntary admissions by companies, alleged breaches of undertakings and information from another complaint.

IFPMA UPDATES CODE OF PRACTICE

The International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) has expanded its Code of Practice to cover how pharmaceutical companies interact with healthcare professionals, medical institutions and patient organisations. All member companies and associations around the world are required to adopt and implement this new Code.

The updated IFPMA Code now also includes:

- high-level guiding principles for practice
- a requirement for member companies to train all employees
- a clear distinction between gifts, promotional aids and items of medical utility
- guidance for supporting continuing medical education
- a provision on disclosure of clinical trials information
- guidance for filing complaints.

The Code continues to prohibit pre-licence promotional activities for medicines, company sponsored entertainment at events and providing or offering personal gifts to healthcare professionals.

Copies of the IFPMA Code can be downloaded from the IFPMA website at www.ifpma.org

Impact on the ABPI Code

Heather Simmonds is the Vice Chair of the IFPMA Code Compliance Network and has been involved with the changes to the IFPMA Code. The PMCPA is looking into how the changes may impact upon the ABPI Code and these will be addressed in any consultation for the next version of the Code. It is anticipated that a new version of the ABPI Code will be published following completion of the Medicines and Healthcare products Regulatory Agency's (MHPRA) consolidation of the medicines regulations. Any changes required due to the IFPMA Code would be addressed at this time.

SOCIAL NETWORKING

The Authority has published guidance on its website (www.pmcpa.org.uk) about the use of digital communication. The guidance discusses how the pharmaceutical industry can use social networking sites, twitter, blogs etc. Given that individuals might also use such means to communicate socially with friends and colleagues, companies are reminded that they would be well advised to issue guidance to staff regarding personal tweets and Facebook entries etc. to ensure that such do not come within the scope of the Code.

CODE OF PRACTICE TRAINING

Training seminars on the Code of Practice, run by the Prescription Medicines Code of Practice Authority and open to all comers, are held on a regular basis in central London.

These seminars comprise a full day course offering lectures on the Code and the procedures under which complaints are considered, discussion of case studies in syndicate groups and the opportunity to put questions to the Code of Practice Authority.

The next Code of Practice seminar date on which places remain available is:
Friday, 23 March

Short training sessions on the Code or full all day seminars can be arranged for individual companies, including advertising and public relations agencies and member and non member companies of the ABPI. Training sessions can be tailored to the requirements of the individual company.

For further information regarding any of the above, please contact Nora Alexander for details (020 7747 1443 or email nalexander@pmcpa.org.uk).

HOW TO CONTACT THE AUTHORITY

Our address is:
Prescription Medicines Code of Practice Authority
7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

www.pmcpa.org.uk

Telephone:	020 7747 8880
Facsimile:	020 7747 8881

Copies of the Code of Practice for the Pharmaceutical Industry and of this Review can be obtained from Lisa Matthews (020 7747 8885 or email lmatthews@pmcpa.org.uk).

Direct lines can be used to contact members of the Authority.

Heather Simmonds:	020 7747 1438
Etta Logan:	020 7747 1405
Jane Landles:	020 7747 1415
Ros Henley	020 7747 8883

The above are available to give informal advice on the application of the Code of Practice.

The Authority rather than the ABPI is the contact point for information on the application of the Code.

HOSPITAL PHYSICIAN v BRISTOL-MYERS SQUIBB

Representatives' training event

A hospital physician complained about an invitation which she had received to participate in a medical representatives' training event. The invitation, sent by an agency on behalf of Bristol-Myers Squibb, stated that the primary aim of the event, which would last just over 2½ hours, was to provide a safe training environment. Clinicians were required to provide written and verbal feedback to representatives regarding their presentation, communication skills and expertise in their therapy area. Invitees were offered an honorarium of £300. The complainant considered that the event in question was unethical. It was simply an underhand way of getting clinicians to accept payment for listening repetitively to sales pitches.

The detailed response from Bristol-Myers Squibb is given below.

The Panel noted that engaging health professionals as consultants to help train representatives was a legitimate activity. However, the arrangements had to be non-promotional and otherwise comply with the Code. The external perception was particularly important given that the health professionals were being paid to listen to and assess the delivery of marketing messages.

The Panel noted that Bristol-Myers Squibb intended to run 13 similar events nationwide; 11 were currently planned. The number of representatives attending each event varied from 2 to 6. Each representative would detail a GP, hospital specialist and nurse specialist and each health professional would be detailed by three representatives. The Panel noted that whilst 77 health professionals had been invited to the meeting at issue only one GP, one nurse and one consultant would actually take part.

The Panel did not accept the company's submission that all documentation made it clear that the agency worked on behalf of Bristol-Myers Squibb. All material was on the agency's stationery on which its logo featured prominently. The Panel was concerned that Bristol-Myers Squibb was not mentioned on the invitation fax back form, which misleadingly described the event as the agency's clinic, and only on the front page of the WebEx briefing pack. Nor did company details appear on the internal feedback forms used at the event in question although the product name was included.

The Panel noted that participating health professionals signed a contract and confidentiality agreement and were briefed before and at the event. The briefing on the day referred to the Code and advised the health professionals to concentrate on the representatives' skills rather than the marketing campaign.

The Panel accepted that the local conditions could be relevant to some aspects of representatives' calls and performance. It queried whether this was so in the matter before it. Bristol-Myers Squibb had not specifically commented on this point. The Panel was very concerned that the arrangements were such that it was highly likely that some of the participating health professionals were those upon whom the same representatives would call in a professional capacity. In the Panel's view it would have been preferable if this was not so. Bristol-Myers Squibb 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 considered that the invitation clearly stated that the event was being organised by the agency on behalf of Bristol-Myers Squibb. The invitation was also clear about the role of invitees: they were to be engaged as independent consultants to participate in a representative training exercise.

The Panel noted that each session between a representative and a health professional was observed by the representative's line manager plus either a second line manager or the product manager who documented their feedback on a form which asked a series of questions about the interaction. The questions were grouped within the following categories; 'Pre-call Planning' 'Connect', 'Understand', 'Position', 'Commit', 'Key Messages' and 'Prescribing'. One question in the 'Understand' category asked 'How effectively did the representative uncover any barriers to your use of Onglyza within your local health economy?'. The 'Commit' category contained the question 'How strongly do you believe that the customer will prescribe Onglyza for specific patient types discussed?'. The Panel was concerned that given the otherwise commercial role of the observers it was not appropriate for them to feedback on business intelligence gathering as an integral part of a training exercise that was meant to be non-promotional. It appeared that the health professional would not have known that this information was being collected.

Each health professional assessor was expected

to complete a similar feedback form about the representative. The questions were grouped within the following categories: 'Engage', 'Understand', 'Position', 'Key Messages' and 'Commitment'. The health professional had to score to what extent the representative had related each of six key promotional messages which were reproduced on the form. Whilst the Panel noted that such assessment could be a legitimate part of a training exercise it queried whether reproducing each promotional claim in full served also to reinforce the promotional message. The Panel queried whether these questions could have been drafted differently. The penultimate question on the form which appeared in the 'Key Message' section was 'Based on this discussion, how likely are you to use/recommend/endorse the use of Onglyza?'. The final question on this form, in the 'Commitment' section, was 'If you would use/recommend/endorse Onglyza please describe the patient profile. If you would not use Onglyza, please explain why'. The Panel noted that the question appeared to be a more general question about the health professional's personal view of the product rather than a question linked to the assessment. Overall the Panel considered that the final question went beyond that legitimately required for the training and development of representatives.

The Panel noted that both of the forms dealt only with positive aspects of the product, and there was no assessment of the representatives' ability to communicate or discuss adverse events.

Consultants were required to complete a questionnaire which gave them an opportunity to express thoughts, *inter alia*, on the products discussed; impact, credibility and value of sales materials; credibility of the discussion, key messages and product positioning. The Panel did not have a copy of the actual questionnaire but noted that its completion appeared to be mandatory. The Panel considered that any assessment of product or sales material was beyond the scope of the training exercise. The Panel noted that the post-event questionnaire was not mentioned in the invitation. In addition, Bristol-Myers Squibb specifically stated that there was no intention to run a potential focus group session or Q&A workshop at the Bristol-Myers Squibb events. This was inconsistent with the briefing pack.

The Panel noted that a contract for a previous training exercise in a different therapeutic area referred to consultants participating in a short focus group session/Q&A workshop or additional questionnaire at the end of the day. A similar statement to the same effect appeared in the contract for the event now in question. The Panel noted Bristol-Myers Squibb's submission that there was no such reference in the contract for the event at issue, that there was no intention to include these at its events and had there been they were events run by the agency for the agency. The Panel noted that Bristol-Myers Squibb was responsible for the acts/omissions of its agency and thus for any focus group/workshop held at a training event. The Panel noted an email wherein the agency organising the event in question stated that no allowance had been made for such workshops to take part or be completed. The Panel noted that the company's response appeared to be inconsistent with the contracts for the events in March and July.

The Panel accepted that discussions between the representative and health professional at a *bona fide* training exercise might indirectly touch on matters that were commercially useful to the company. However, it was unacceptable for the company to solicit or otherwise assess matters which went beyond the scope of the training exercise. The Panel considered that some of the information assessed and collected in both feedback forms could only be used for promotional purposes, rather than for the training and development of representatives.

Taking all the circumstances in to account, the Panel did not consider that the event was a *bona fide* training event. The assessment forms and the local nature of the activity as discussed above, in the absence of safeguards, rendered the training session promotional. It was disguised in this regard and a breach of the Code was ruled.

The Panel noted its concerns set out above. Bristol-Myers Squibb 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 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. The Panel noted the criteria set out for the hiring of consultants. 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 of the Code and a breach was ruled.

Upon appeal by Bristol-Myers Squibb 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 was whether any promotion as a consequence of the training at issue was necessary, proportionate, and transparent. The first element to be considered was whether the activity was disguised promotion.

The Appeal Board noted that 77 health professionals had been invited to participate in the event and only the first GP, nurse and consultant to respond were engaged. The event had been organised to assess the performance of three representatives. According to Bristol-Myers Squibb neither it nor the representatives knew the identity of the health professionals that would participate in the event until the day. The three health professionals had each seen the three representatives giving a total of nine assessed interviews. In that regard the Appeal Board did not consider that the number of assessments per health professional was unreasonable.

The Appeal Board noted the company's submission that many of the materials submitted to the Panel were in draft form and that the feedback forms, when submitted to the Authority, had not been certified. The company submitted that it had adjusted the wording on the final version of the assessment forms to clarify that the questions related to the representative's role-play performance and not to the future real life prescribing habits of the health professional. The Appeal Board noted that the company had not provided the actual forms used at the assessment in July. The forms provided with the letter of appeal (dated 1 September) were the same as those provided to the Panel. In response to a question at the appeal hearing the representatives stated that the form had been changed and questions such as 'If you would use/recommend/endorse Onglyza please describe the patient profile. If you would not use Onglyza, please explain why' queried by the Panel had not been used. In the Appeal Board's view it seemed unlikely that the documents had been changed in light of the Panel's comments, as implied, given that the company was informed of the Panel's rulings on 17 August which was after the event had taken place. The Appeal Board noted that it would have been greatly assisted if copies of the documents actually used had been provided. It would also have been helpful if the draft copies supplied to the Panel had been clearly marked as such.

The Appeal Board noted that Bristol-Myers Squibb only received anonymised data generated from the training event regarding the health professionals' opinions etc. It was not otherwise used for a commercial purpose and the prescribing habits of the health professionals were not monitored. The representatives, however, were ranked and the information used to address further training needs.

The Appeal Board also queried an apparent inconsistency in the company submissions as the health professional pre-event brief stated that no role-play was required – 'simply behave as you would normally in your place of work' whereas in its appeal, Bristol-Myers Squibb submitted that there was no indication that the information offered by the health professionals reflected the true scenario of their local units given the role-play environment. At the appeal hearing the view of those representing the company was in line with the pre-event brief and the health professional briefing pack which stated 'No role-playing is required; be the same as you would at your place of work'.

The Appeal Board considered that an unavoidable consequence of the training event would be the promotion of Onglyza and in that regard it was concerned that the repetition of key positive messages on the feedback form would reinforce those messages. There was no assessment of how the representatives discussed side effects. Nonetheless, on balance, the Appeal Board did not consider that the training event was disguised promotion. No breach of the Code was ruled. As a consequence of that ruling the Appeal Board considered that the other rulings of breaches also fell. No breaches of those clauses were ruled. The appeal was thus successful.

A hospital physician complained about an invitation which she had received to participate in a medical representatives' training event. The invitation, sent by a training service agency on behalf of Bristol-Myers Squibb Pharmaceuticals Limited, stated that the primary aim of the event was to provide a safe training environment. Diabetologists were required to provide written and verbal feedback to representatives regarding their presentation, communication skills and expertise in their therapy area. An honorarium of £300 would be paid for the event which ran from 14.40 hours to 17.05 hours.

COMPLAINT

The complainant considered that the event in question was unethical. It was simply a very underhand way of getting clinicians to accept payment for listening repetitively to sales pitches.

When writing to Bristol-Myers Squibb, the Authority asked it to respond in relation to Clauses 12.1, 18.1 and 20.1 of the Code.

RESPONSE

Bristol-Myers Squibb explained that the training event in question was intended to provide representatives with a safe training environment in which they could practice and learn from experienced local health professionals whilst they were working out in the field.

Bristol-Myers Squibb knew of five companies that ran such events, the company currently used by Bristol-Myers Squibb had run these events for 19 different pharmaceutical companies and multiple brands over the last four years. Events were run in regional and national venues or at the health professionals' office/hospital/surgery. Health professionals were paid honoraria for their time which might include travel expenses if not held in their own office/hospital/surgery. Room rental was

only paid if a third party venue was used. Bristol-Myers Squibb only intended to run these events in third party venues in order to ensure separation between promotional and non-promotional (in this case) activities.

Bristol-Myers Squibb submitted that the invitation was clear from the start that this was a training event for medical representatives. The reason for choosing health professionals with an understanding of the therapy area concerned was to ensure the training environment was as close to reality as possible. This meant representatives were asked real and relevant questions. Details of the briefing with the agency were provided. The briefing specifically asked that the agency chose health professionals with a diabetes background. This was important as the company wished to make the detail relevant to its representatives and the health professionals involved.

Once the health professional agreed to be part of the training event a letter was sent confirming details of the venue, time, date and honoraria. Again it was made very clear that this was a representative training event.

Health professionals were provided with a briefing pack which gave them a clear understanding of what was required of them during the event. The meeting to which the complainant had been invited would take three hours in total, although it was unlikely the health professional would be required for more than 2½ hours. During the afternoon each health professional would be detailed by three representatives. These sessions would be observed by the line manager and either a second line manager or product manager. The call would last for about 20 minutes and the health professional was expected to provide verbal feedback for 5 minutes; they were then given 10 minutes to provide written feedback. So each health professional spent 25 minutes with each representative. Copies of feedback forms were provided.

Bristol-Myers Squibb stated that the health professional was sent a combined contract/confidentiality agreement which clearly stated that this was a representative training event. A description of the work expected was given along with timings and venue. Fees/honoraria were given as well as recommendations regarding declaration of employment. Finally, there was a section on confidentiality. The agreement was signed by the marketing support consultancy and the named health professional. In all documentation it was clear that the consultancy worked on behalf of Bristol-Myers Squibb.

Bristol-Myers Squibb stated that it was not involved directly in negotiating honoraria payments however, it provided the marketing support consultancy with guidelines, details of which were provided.

With regard to the series of events in question, Bristol-Myers Squibb intended to run up to 13. Details of the 11 currently planned were provided. Each representative would detail a GP, hospital specialist and nurse specialist. Following a request for further information, Bristol-Myers Squibb confirmed that 13 nurses, 37 general practitioners and 27 consultants had been invited to participate in the event at issue.

Bristol-Myers Squibb stated that the event was and always had been intended as a legitimate representative training event on call quality. It was very clear in all the related materials that this was the purpose of the event and therefore it was not disguised promotion. The only payments made to the health professionals was for their time worked at the event and not as an inducement to prescribe, supply, administer, recommend, buy or sell any Bristol-Myers Squibb medicine. A written contract was available to all health professionals who agreed to participate. Bristol-Myers Squibb denied any breach of Clauses 12.1, 18.1 and 20.1.

Following a request for further information, Bristol-Myers Squibb confirmed that the event at issue was operated on a first come first served basis. The first nurse to respond would be the person used, and the same for the GP and hospital consultant. As stated previously, there would only be one GP, one nurse and one consultant actually taking part.

In relation to the reference to a focus group session/Q&A workshop in the contract for a similar training event on 30 March 2011, Bristol-Myers Squibb explained that there was no intention to include these at its events. Had there been, these were events run by the agency for the agency.

PANEL RULING

The Panel noted that the complainant alleged that the event was unethical. The complainant had not attended the training.

The Panel noted that engaging health professionals as consultants to participate in training of representatives was a legitimate activity. However, all of the arrangements for such activities must be non-promotional and otherwise comply with the Code. The external perception was particularly important given that the health professionals were being paid to listen to and assess the delivery of marketing messages.

The Panel noted that Bristol-Myers Squibb intended to run 13 similar events nationwide, 11 of which were currently planned. The number of representatives attending each event varied from 2 to 6. Each representative would detail a GP, hospital specialist and nurse specialist and each health professional would be detailed by three representatives. The Panel noted that whilst 77 health professionals had been invited to the meeting at issue only one GP, one nurse and one consultant would actually take part.

The Panel did not accept the company's submission that in all documentation it was clear that the agency worked on behalf of Bristol-Myers Squibb. All material was on the agency's stationery on which its logo featured prominently. The Panel was concerned that Bristol-Myers Squibb was not mentioned on the invitation fax back form, which misleadingly described the event as the agency's clinic, and only on the front page of the WebEx briefing pack. Nor did company details appear on the internal feedback forms used at the event in question although the product name was included.

The Panel noted that participating health professionals signed a contract and confidentiality agreement which set out the terms of the consultancy and upon registration were provided with a pre-event brief followed by a full briefing immediately before the event. The full briefing referred to the Code and advised participating health professionals to concentrate on the representatives' skills rather than the marketing campaign.

The Panel accepted that the local conditions could be relevant to some aspects of representatives' calls and performance. It queried whether this was so in the matter before it. Bristol-Myers Squibb had not specifically commented 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 upon whom they were expected to call. Bristol-Myers Squibb 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 examined the invitation which clearly stated that the event was being organised by the agency on behalf of Bristol-Myers Squibb. The Panel considered that the invitation was clear about the role of invitees: they were to be engaged as independent consultants to participate in a representative training exercise.

The Panel noted that each session between a representative and a health professional was observed by the representative's line manager plus either a second line manager or the product manager who documented their feedback on a form which asked a series of questions about the interaction. The questions were grouped within the following categories; 'Pre-call Planning' 'Connect', 'Understand', 'Position', 'Commit', 'Key Messages' and 'Prescribing'. One question in the 'Understand' category asked 'How effectively did the representative uncover any barriers to your use of Onglyza within your local health economy?'. The 'Commit' category contained the question 'How strongly do you believe that the customer will prescribe Onglyza for specific patient types discussed?'. The Panel was concerned that given the otherwise commercial role of the observers it was not appropriate for them to feedback on business intelligence gathering as an integral part of a training exercise that was meant to be non-promotional. It appeared that the health professional would not have been aware that this information was being collected.

Each health professional assessor was expected to complete a similar form to provide feedback on the representative. The questions were grouped within the following categories: 'Engage', 'Understand', 'Position', 'Key Messages' and 'Commitment'. The health professional had to score to what extent the representative had related each of six key promotional messages which were reproduced on the form. Whilst the Panel noted that such assessment could be a legitimate part of a training exercise it queried whether reproducing each promotional claim in full served also to reinforce the promotional message. The Panel queried whether these questions could have been drafted differently. The penultimate question on the form which appeared in the 'Key Message' section was 'Based on this discussion, how likely are you to use/recommend/endorse the use of Onglyza?'. The final question on this form, in the 'Commitment' section, was 'If you would use/recommend/endorse Onglyza please describe the patient profile. If you would not use Onglyza, please explain why'. The Panel noted that the question appeared to be a more general question about the health professional's personal view of the product rather than a question linked to the assessment. Overall the Panel considered that the final question went beyond that legitimately required for the training and development of representatives.

The Panel noted that both of the forms dealt only with positive aspects of the product, and there was no assessment of the representatives' ability to communicate or discuss adverse events.

The penultimate slide in the Healthcare Professional Briefing Pack gave details of a Post-Event Questionnaire which the consultants were required to complete at the end of the day on site. The questionnaire was designed to be the consultants' opportunity to express thoughts, *inter alia*, on the products discussed; impact, credibility and value of sales materials; credibility of the discussion, key messages and product positioning. The Panel had not been provided with a copy of the actual questionnaire but noted that its completion appeared to be mandatory. The Panel considered that any assessment of product or sales material was beyond the scope of the training exercise. The Panel noted that the post event questionnaire was not mentioned in the invitation. In addition, Bristol-Myers Squibb specifically stated that there was no intention to run a potential focus group session or Q&A workshop at the Bristol-Myers Squibb events. This was inconsistent with the Bristol-Myers Squibb

Healthcare Professional Briefing Pack.

The Panel noted that it had been provided with a copy of a contract for a training exercise which had apparently already taken place in March in a different therapeutic area and which referred to consultants participating in a short focus group session/Q&A workshop or additional questionnaire at the end of the day. A similar statement appeared in the contract for the event in question which stated 'At the end of the day you may be required to complete short focus group questionnaire giving your general feedback on your observations of the day'. The Panel noted Bristol-Myers Squibb's submission that there was no such reference in the contract for the event at issue, that there was no intention to include these at its events and had there been they were events run by the agency for the agency. The Panel noted that Bristol-Myers Squibb was entirely responsible for the acts/omissions of its agency and consequently was responsible for any focus group/workshop held at a training event. The Panel noted an email wherein the agency organising the event in question stated that no allowance had been made for such workshops to take part or be completed. The Panel noted that the company's response appeared to be inconsistent with the contracts for the events in March and July.

The Panel accepted that during discussions between the representative and health professional at a *bona fide* training exercise the conversation might indirectly touch on matters that were commercially useful to the company. However, it was unacceptable for the company to solicit or otherwise assess matters which went beyond the scope of the training exercise. The Panel considered that some of the information assessed and collected in both feedback forms could only be used for promotional purposes, rather than for the training and development of representatives.

Taking all the circumstances in to account, the Panel did not consider that the event was a *bona fide* training event. The assessment forms and the local nature of the activity as discussed above, in the absence of safeguards, rendered the training session promotional. It was disguised in this regard and a breach of Clause 12.1 was ruled.

The Panel noted its concerns set out above. Bristol-Myers Squibb 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. 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. A breach of that clause was thus ruled.

APPEAL BY BRISTOL-MYERS SQUIBB

Bristol-Myers Squibb stated that it had supplied a considerable amount of evidence to the Panel regarding the specific event in July and other, similar, events organized around the country. As indicated to the Panel, there was considerable value in engaging real health professionals for these events because only practising health professionals reacted in a genuine fashion to the attitude and techniques of the representatives in front of them. Feedback from actual customers was therefore of great value to the successful skill development of representatives. However, in all cases the feedback from health professionals was complemented by observation of the interactions by experienced managers and sales training staff to ensure that the technical aspects of the sales call were also covered and assessed.

Bristol-Myers Squibb submitted that following an earlier (unrelated) training event which the training service agency had run for the company in March, a series of 13 new training events were planned during the summer. At the time of the complaint, recruitment had begun for the summer events in order to secure sufficient numbers of health professionals, but the detailed content of the assessment was still being developed (the complaint was received more than 5 weeks before the first training event).

The scope of the complaint

Bristol-Myers Squibb noted that the complaint was only two sentences: 'I consider this sort of event to be unethical. It is simply a very underhand way of getting clinicians to listen to repetitive sales pitches'.

The complainant was therefore:

- Clear that the event was run on behalf of a pharmaceutical company
- Challenging the validity of the concept
- Not raising particular concerns about the Bristol-Myers Squibb event in July
- Complaining about being paid to listen to a repetitive series of 'pitches'.

Bristol-Myers Squibb noted that as the complaint was submitted over a month before the event,

many of the materials the Authority had requested were still in draft form and the Panel had based its rulings on what *might* happen rather than what actually happened. This was a matter of some significant concern. Nevertheless the draft documents were submitted in good faith to support the legitimacy of the event in general.

Bristol-Myers Squibb also noted that the complainant did not raise concerns about:

- Seeing a particular representative during the training
- The transparency of Bristol-Myers Squibb's' involvement in the event
- The organization of the event
- How information gathered at the event might be used in the future
- The honorarium being inappropriate for the time and work expected

Bristol-Myers Squibb submitted that while it defended the fact that all aspects of the training were legitimate, it noted that the five points above were all matters considered by the Panel in its rulings despite the fact that they were not raised by the complainant. This in itself should invalidate the Panel's rulings because the Panel had included broader aspects of the event that were outside the scope of the complaint and also the legitimate scope of relevant enquiry necessary to assess this case. Nonetheless, Bristol-Myers Squibb also contended that the Panel's conclusions in respect of these matters were incorrect.

Bristol-Myers Squibb would address each point raised by the Panel in turn. However, the Panel's rulings regarding Clauses 18.1 and 20.1 appeared to be based solely on its determination of the event as disguised promotion (Clause 12.1). Bristol-Myers Squibb would challenge each of the rulings separately, but would expect that if the breach of 12.1 was overturned, then the rulings of breaches of Clauses 18.1 and 20.1 must also be overturned.

Bristol-Myers Squibb recognized that some aspects of the organisation of the planned training event might have been more tightly controlled and it had already taken steps to address the learning from this case. However, it noted that there were no concerns raised regarding the organization of the event (by the complainant or in the Panel's ruling) and Bristol-Myers Squibb reiterated that some aspects of the event were not fully approved by company signatories when Bristol-Myers Squibb's submitted its response.

Disguised promotion

Bristol-Myers Squibb noted that the Panel recognized that it was legitimate to involve health professionals in representative training events so long as the arrangements were in accordance with the Code. Therefore the general point made by the complainant was already dealt with - in general these events were acceptable. The question must then turn to the specifics of this particular event.

Bristol-Myers Squibb submitted that it had been difficult for it to determine exactly why the Panel regarded the event as disguised promotion. Whilst the Panel raised some comments in the discussion leading towards its ruling, Bristol-Myers Squibb submitted that none appeared to justify its conclusion. If the event was 'disguised promotion' then one or more of the following must be true:

- The health professionals did not expect to receive information about company products

Bristol-Myers Squibb submitted that the complainant clearly expected to receive information about company products; that was the entire basis for the complaint. Therefore this could not be the basis for a ruling of disguised promotion. The Panel noted that the documentation did not consistently state Bristol-Myers Squibb's involvement. This was dealt with under Clause 9.10 of the Code (not Clause 12.1). Nevertheless, the two specific examples highlighted by the Panel in its ruling were of some concern to Bristol-Myers Squibb.

The faxback form was intended to be faxed back to the event organizers. It was difficult to see the necessity of including the pharmaceutical company name/logo on this form given that it was more important for the form to clearly state to whom it should be returned. However, the faxback form would, of course, not even be seen unless the health professional had received the invitation which clearly and unambiguously stated in the first line that the event was organized for Bristol-Myers Squibb.

With regard to the second example cited by the Panel (the assessment forms used on the day) Bristol-Myers Squibb submitted that it was virtually impossible for anyone on the day not to know the event was connected with Bristol-Myers Squibb given that every representative had used Bristol-Myers Squibb sales material and introduced themselves as being from Bristol-Myers Squibb. The assessment forms would, of course, not be seen by any health professional who was not at the event. The Panel's comments were therefore confusing in this regard. Every health professional invited to the event or attending the event would expect to receive practice sales pitches about Bristol-Myers Squibb products. The absence of the Bristol-Myers Squibb name on a couple of pieces of supplementary paper therefore could not conceivably be the basis for disguised promotion of a pharmaceutical product.

- The health professionals were subjected to an unreasonable number of sales pitches on the day such that the combined weight of pitches amounted to an intense sell

Bristol-Myers Squibb noted that repetitive sales pitches were the only specific issue raised by the complainant. As was clearly identified in Bristol-

Myers Squibb's documentation, each health professional received three sales pitches from different representatives. Three calls in three hours did not represent an intention to 'bombard' the health professional with constant messages. This therefore could not credibly be the basis for a ruling of disguised promotion.

- The health professionals were individually chosen for the event in order to achieve a commercial purpose

Bristol-Myers Squibb submitted that seventy-seven health professionals in three professions (pharmacy, nursing and physician) were invited in order to secure the services of one from each profession. This meant that the selection of health professionals for the specific event was reasonably random. There was no suggestion and certainly no intent to identify specific health professionals in order to meet any local targeting objectives. In fact the representatives who were assessed on the day did not know which health professionals would be present until they arrived. If the intention had been to target specific health professionals for commercial reasons then the recruitment would not be on a first-come first-engaged basis, but according to a definitive list of health professionals in a definitive order of preference. This was clearly not the case, nor was it the allegation. This therefore could not credibly be the basis for a ruling of disguised promotion.

- The outputs of the event were used for commercial purposes at an individual health professional or health organization level

Bristol-Myers Squibb submitted that the event might be considered as disguised promotion if the outputs were used for commercial purposes. This was implied by the Panel but was not raised as a concern by the complainant. Bristol-Myers Squibb maintained a comprehensive coaching system for all its representatives where learning objectives were stored and tracked. The outputs from this event would be entered into this training system so that area managers could use the information to structure ongoing in-field training in a representative-specific manner. The training exercise would identify areas upon which the representatives needed to focus in order to improve their sales skills. At the end of each day's training the managers present would meet to discuss the individual representatives and agree the specific areas of future focus.

Bristol-Myers Squibb noted that the Panel raised concerns in respect of the nature of information identified and tracked during the individual assessments. One particular concern raised by the Panel, but not by the complainant, was in respect of information about the individual health organizations at which the health professionals worked.

It was important to note in this regard, firstly, that no information about the individual health organizations was recorded in any database (commercial or otherwise).

Secondly, the allocation of the Bristol-Myers Squibb observers was random in relation to both the representatives and the health professionals; any assessor could have been paired with any representative or health professional. This meant that some of the observers would not know who the health professionals were and would not have necessarily even known which healthcare organizations they worked at. The selection of the health professionals was random, so if the intention had been to uncover meaningful information then the selection of the health professionals would have been controlled to optimize the information-gathering opportunities.

Finally, Bristol-Myers Squibb submitted that there was no indication that the information offered by the health professionals was reflective of the true scenario in their local units. In a role-play environment the focus was on the interactions and the way the representative reacted to the comments from the 'customer'; there was no need for the customer to be completely truthful about his/her local environment so long as the comments could reflect real life in the local health economy.

Bristol-Myers Squibb submitted that a second concern raised by the Panel (but again, not by the complainant) was in respect of the questions asked on the assessment form. At this point it was important to reflect on the typical structure of a sales call. Representatives were trained to open a call clearly, establish rapport with the customer, deliver specific messages in respect of the product concerned, uncover any objections and to close the call by asking for a commitment to prescribe where appropriate. Clearly these were the areas that should therefore be assessed in any training programme. Bristol-Myers Squibb noted that health professionals were used in this type of training programme because only they could react naturally to the sales pitch in the way that they might in a real scenario. It was therefore reasonable to ask the health professionals how they reacted to the sales pitch. This was not a commitment to prescribe in real life, but an assessment of whether the interaction with the representative was convincing enough that based on the information provided they would give a commitment in the role-play scenario. The Panel appeared to have regarded this as a commitment to prescribe in real life, which was not the intent.

The Panel had further commented that the assessment forms reproduced key messages for the products. This was deliberate; how could the health professionals comment on whether the messages were delivered if they did not know what to look for? Whilst Bristol-Myers Squibb accepted that there was a possibility that seeing the messages written down might reinforce the promotional message, this was purely an incidental effect and by no

means the intent of the exercise.

Bristol-Myers Squibb submitted that the feedback from an individual health professional was not transferred to the customer record in its sales database or communicated to the representatives who would call on that health professional in real life. Such recording and sharing such information would be completely inappropriate. Regardless, this was not the case and there was no allegation in this regard.

Bristol-Myers Squibb noted that the penultimate slide of the briefing notes instructed health professionals to focus on the selling skills (ie whether the marketing messages were delivered) and not to comment on the viability of the marketing messages themselves. This was to ensure that the feedback to the representatives was as focused as possible.

Bristol-Myers Squibb reiterated that the forms assessed by the Panel were still in draft form and had not been certified as the event was still over a month away. The company, however, was grateful to the Panel for the feedback regarding its interpretation and had adjusted the wording on the final version of the assessment forms to clarify that the questions related to the representative's role-play performance and not to the future real life prescribing habits of the heath professional in question. This therefore could not credibly be the basis for a ruling of disguised promotion.

- The entire event was not intended for training purposes at all, but was simply an excuse to expose health professionals to promotional messages

Bristol-Myers Squibb submitted that only three health professionals were sought for the event. Given that only three were engaged from the seventy seven contacted, Bristol-Myers Squibb contend that there was no foundation for regarding the intention or implementation of the event as designed to expose health professionals to promotional messages.

The Panel raised an additional concern in respect of the possibility of an individual representative practising a sales call opposite their own customer. Bristol-Myers Squibb acknowledged that this would have happened in the meeting at issue because the three representatives all covered all of the country in which it took place. However there was no indication in the Code that representatives and their customers needed to be separated in such a situation.

Moreover, one of the reasons that practising with real health professionals was so important was that their responses were indicative of the general health environment in which they worked. For example, allowing representatives from one country to practice with health professionals from another country would be of limited benefit as the health systems in the two countries were sufficiently different that the response of the health professionals would be less relevant to representatives from such a different geography. This therefore could not credibly be the basis for a ruling of disguised promotion (Clause 12.1).

Overall, Bristol-Myers Squibb found no justification for the Panel's ruling of disguised promotion. Participants expected to be involved in practice sales calls; the event was a genuine training event with no pre-selection of health professionals or generation of commercial outputs other than training objectives.

Inducement to prescribe

Bristol-Myers Squibb submitted that the Panel's ruling of Clause 18.1 appeared to be primarily based on the fact that it considered that the training event was disguised promotion in breach of Clause 12.1. Bristol-Myers Squibb contended above that the ruling of Clause 12.1 was unjustified and therefore also sought to have the ruling of a breach of Clause 18.1 overturned.

Bristol-Myers Squibb fully supported the fact that breaches of Clause 18.1 should be regarded as very serious breaches of the Code.

However, Bristol-Myers Squibb submitted that ruling it in breach for this activity effectively stated that the company had paid health professionals to listen to promotional messages. Even if some aspects of the event could have been better managed, there was nothing in the way it was planned or implemented to imply that the payments were inappropriate or made for anything other than legitimate purposes.

Bristol-Myers Squibb submitted that the amounts involved were within industry norms and there was no discussion from the Panel about the amount of work involved for the fees stated. Hospital physicians and GPs received £300 (including expenses) for the event; nurses only £200 (including expenses).

Bristol-Myers Squibb noted the Panel's comments in relation to the lack of separation between the training event and subsequent professional contact. Bristol-Myers Squibb saw how it would be beneficial to remind representatives not to raise the subject of the training event with those limited numbers of health professionals who did attend such an event. However this was no different to instructing representatives not to discuss the detail of a speaking engagement with a health professional engaged as a speaker. It was a standard element of representative professional behaviour not to confuse service engagement with promotional calls.

However there was no allegation about a representative referring to the training event during a sales call and therefore it was difficult to see how

the Panel's comments in respect of such a hypothetical situation were justified. Whilst Bristol-Myers Squibb recognized the limited potential for such an inappropriate discussion, it did not consider that this vague possibility justified ruling a breach of Clause 18.1 as the Panel seemed to have implied in its ruling.

Bristol-Myers Squibb therefore submitted that the ruling of a breach of Clause 18.1 should be overturned.

Inappropriate engagement of services

Whilst Bristol-Myers Squibb recognized that a breach of Clause 20.1 automatically registered a breach of Clause 18.1 (under the supplementary information to Clause 18.1), the Panel appeared to have made its ruling regarding Clause 18.1 first.

Therefore the Panel must have made its ruling of a breach of Clause 20.1 as a stand alone decision.

Regardless, Bristol-Myers Squibb did not agree with the ruling of a breach of Clause 20.1.

The Panel in its ruling referred to the issues in respect of breaches of Clauses 12.1 and 18.1. As presented above, Bristol-Myers Squibb submitted these rulings were not justified and should be overturned.

Nevertheless, Bristol-Myers Squibb had considered the aspects of Clause 20.1 in isolation. Even if the event could have been better managed, Bristol-Myers Squibb contended that the overall event justified the legitimacy of the services provided by the health professionals.

Bristol-Myers Squibb noted that the health professionals were expected to work for approximately 3 hours. It was difficult to see that the payment could be regarded as inappropriate for the time commitment. The work was genuine, as evidenced by the need to complete assessment forms and provide verbal feedback, in addition to attending a Webex briefing.

As discussed above, the Panel had some issues in respect of the questions asked on the assessment forms, however Bristol-Myers Squibb submitted that these were legitimate questions asked in a training environment. There was also no guarantee that the information provided by the health professionals in a training environment was completely accurate, and indeed no comments made by the health professionals were transferred from the training record to the commercial database used for recording real life sales call information.

Bristol-Myers Squibb noted that, in response to a request for further information, it had previously supplied the Panel with copies of the slides planned for use in the Webex briefing for the health professionals. Attendance at the Webex also constituted part of the payment of services. Bristol-Myers Squibb contended that the draft slides were supplied in good faith in advance of the briefing.

With regard to the Panel's observations in respect of the additional session that was potentially to have been run by the agency on the day, and which was mentioned on the slides and in the contract, Bristol-Myers Squibb noted that no complaint was made about this matter. Even if there had been, this would have constituted additional work by the health professionals on the day, further justifying the level of service they were expected to provide.

Bristol-Myers Squibb also disputed the Panel's comments that such a workshop would have been inappropriate. There was nothing in the Code to prevent the optimal use of time in respect of the engagement of services from health professionals. Bristol-Myers Squibb submitted that it would have been acceptable for it to have run such feedback sessions and a training programme on the same day with the same attendees, as long as both were genuine non-promotional activities. When it made its ruling the Panel had not reviewed any agenda or planned content for the additional workshop so it was difficult to see the relevance of its comments to the content of the feedback session. However, since the feedback session did not take place, the Panel's comments were irrelevant to the ruling in this case.

Bristol-Myers Squibb noted that the complainant did not raise any concerns in relation to the organization of the training event or the inclusion of a feedback session; the complaint was about 'repetitive sales pitches'. The Panel had thus exceeded the scope of the complaint in considering this hypothetical additional session.

Bristol-Myers Squibb noted that whilst feedback workshops were part of the standard offering from a training service agency to pharmaceutical companies, they were not intended to form part of its event.

Bristol-Myers Squibb considered the ruling of a breach of Clause 20.1 was unjustified.

Bristol-Myers Squibb asked the Appeal Board to overturn the Panel's rulings of breaches of Clause 12.1, 18.1 and 20.1 in respect of the training event which had not taken place when the Panel made its ruling.

RESPONSE FROM THE COMPLAINANT

The complainant had no further comments to make on the details of the case. The complainant stated that in making her complaint, she believed that she was handing it over, so that it was PMCPA vs Bristol Myers Squibb, - the procedures seemed to expect 'individual' or 'company' vs BMS. No individual had the resources to do much beyond alerting the Authority to what he/she believed to be a breach of the Code.

The complainant alleged that it was clear, as

exemplified by this case, and another case, that these training events which had happened for years, and were used by many pharmaceutical companies, were sophisticated disguised promotional events. Companies would continue to find clever ways to conceal this fact. The complainant queried whether the PMCPA had ruled on similar cases in the past and if so, had it any role in the monitoring of pharmaceutical company activities, or was it a purely reactive role to individual complaints? The complainant also queried whether there was any mechanism whereby companies must themselves monitor their compliance with ABPI guidelines, and if so, had any documentation relating to compliance checks for the events, which were the subject of these cases, been received by PMCPA? In both the cases the cycle of training events was over, so even if the appeals were lost by the companies, it would seem they suffered no loss apart from the expense and trouble of defending their cases.

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 that 77 health professionals had been invited to participate in the event and only the first GP, nurse and consultant to respond were engaged. The event had been organised to assess the performance of three representatives. According to Bristol-Myers Squibb neither it nor the representatives knew the identity of the health professionals that would participate in the event until the day. The three health professionals had each seen the three representatives giving a total of nine assessed interviews. In that regard the Appeal Board did not consider that the number of assessments per health professional was unreasonable.

The Appeal Board noted the company's submission that many of the materials submitted to the Panel were in draft form and that the feedback forms, when submitted to the Authority, had not been certified. The company submitted that it had adjusted the wording on the final version of the assessment forms to clarify that the questions related to the representative's role-play performance and not to the future real life prescribing habits of the health professional. The Appeal Board noted that the company had not provided the actual forms used at the assessment. The forms provided with the letter of appeal (dated 1 September) were the same as those provided to the Panel. In response to a question at the appeal hearing the representatives stated that the form had been changed and questions such as 'If you would use/recommend/endorse Onglyza please describe the patient profile. If you would not use Onglyza, please explain why' queried by the Panel had not been used. In the Appeal Board's view it seemed unlikely that the documents had been changed in light of the Panel's comments, as implied, given that the company was informed of the Panel's rulings on 17 August which was after the event had taken place. The Appeal Board noted that it would have been greatly assisted if copies of the documents actually used had been provided. It would also have been helpful if the draft copies supplied to the Panel had been clearly marked as such.

The Appeal Board noted that data generated from the training event regarding the health professionals' opinions etc was anonymised before being given to Bristol-Myers Squibb. It was not otherwise used for a commercial purpose and the prescribing habits of the health professionals were not monitored. The representatives, however, were ranked and the information used to address further training needs.

The Appeal Board also queried what appeared to be an inconsistency in the company submissions as the healthcare professional pre-event brief stated that no role-play was required – 'simply behave as you would normally in your place of work' whereas in its appeal, Bristol-Myers Squibb submitted that there was no indication that the information offered by the health professionals reflected the true scenario of their local units given the role-play environment. At the appeal hearing the view of those representing the company was in line with the pre-event brief and the Healthcare Professional Briefing Pack which stated 'No role-playing is required; be the same as you would at your place of work'.

The Appeal Board considered that an unavoidable consequence of the training event would be the promotion of Onglyza and in that regard it was concerned that the repetition of key positive messages on the feedback form would reinforce those messages. There was no assessment of how the representatives discussed side effects. Nonetheless, on balance, the Appeal Board did not consider that the training event was disguised promotion. No breach of Clause 12.1 was ruled. As a consequence of that ruling the Appeal Board considered that the rulings of breaches of Clauses 18.1 and 20.1 also fell. No breaches of those clauses were ruled. The appeal was thus successful.

Complaint received **16 July 2011**

Case completed **16 November 2011**

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**

GENERAL PRACTITIONER v BOEHRINGER INGELHEIM and LILLY

Sponsored article on linagliptin

A general practitioner complained that an article on linagliptin published in Future Prescriber represented the exaggerated, misleading and disguised promotion of linagliptin before a UK marketing authorization had been granted.

The article 'Linagliptin: new class of DPP-4 [dipeptidyl peptidase-4] inhibitor in the treatment of T2DM [type 2 diabetes mellitus]' was written by two diabetes and endocrinology physicians. A declaration of the authors' interests was given in the final paragraph which stated 'Placement of this article has been funded by Boehringer Ingelheim and Lilly. The content has been independently commissioned by Future Prescriber and has been checked by Boehringer Ingelheim and Lilly for factual accuracy only. Editorial control of this article remains with Future Prescriber'.

The complainant stated that the authors had previously received support from the companies which suggested that their opinions were likely to be known by both the companies which were likely to have been involved in their selection and briefing.

The complainant noted that the article stated that linagliptin was now approved and due to launch in the UK; this was not so. Linagliptin had only received a positive opinion from the European Medicines Agency (EMA).

The complainant alleged that the title of the article was misleading and exaggerated. He knew of no recognised or accepted sub-class of DPP-4 inhibitors. The title suggested an unqualified and unsubstantiated superiority over currently licenced DPP-4 inhibitors, comparisons with which were made throughout the article.

The complainant asked if it was accurate to compare the maximal efficacy and potency of linagliptin with other DPP-4 inhibitors or claim that, in relation to use with concomitant medicines, linagliptin was safer than saxagliptin (Onglyza); especially given that there were no head-to-head data with other DPP-4 inhibitors to substantiate this.

The complainant alleged that the claim that linagliptin might have a positive and long enduring effect on beta-cell function and therefore glycaemic control was misleading and inaccurate; this was not a fact nor could it be substantiated. The complainant stated that an unbalanced and distorted promotional message was also elaborated with regard to renal acceptability. Saxagliptin was currently the only DPP-4 inhibitor with a UK licence for use in moderate/severe renal impairment. The complainant further alleged that the discussion of the possible cost of linagliptin compared with other DPP-4 inhibitors was not factual and potentially misled about cost-efficacy.

The complainant alleged that the decision to fund the development of this article and the evident lack of proper scrutiny of the facts suggested that the companies were keen to promote linagliptin prior to licence.

The detailed responses from Boehringer Ingelheim and Lilly are given below.

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.

The Panel noted that the publishers of Future Prescriber has proposed *inter alia*, two complementary articles (one of which was the article in question) as part of the 'managed entry programme' for linagliptin 'to support the product' and 'prepare the market'. It was proposed that the article in question would examine current and future treatment options with particular focus on the DPP-4 class and forthcoming products. The proposal also stated that the article would be independently commissioned, peer reviewed and published within the main pages of the journal. There would be no input from the company other than for medical accuracy. Reprints would be made available following publication. Minutes of a meeting between Boehringer Ingelheim the publishers and Lilly once the complaint had been received stated, *inter alia*, that the agreement with the publisher was that it would take all responsibility for generation of the article, choosing of authors (although it could request

input from Boehringer Ingelheim, as it had done in relation to the article in question, but the publishers had made the final choice), managing the writing and review process and publication of the final article.

The Panel considered that it was clear from the proposal that the article would support linagliptin, and that Boehringer Ingelheim would have known this at the outset.

It appeared that although Boehringer Ingelheim did not pay for the article *per se*, it in effect commissioned it through an agreement to pay for 2,000 reprints. The Panel considered that Boehringer Ingelheim was inextricably linked to the production of the article and the company was responsible under the Code for the content.

Turning to the article itself, the Panel noted that the only mention of Boehringer Ingelheim was at the end of the article, after citation of all the references. The Panel considered that the article did not clearly indicate the involvement of the company, and ruled a breach of the Code. As the content was promotional, the Panel considered that it was disguised in that regard and ruled a breach of the Code.

The Panel noted that the article stated that linagliptin was approved in the UK. When the article was published, the product had not received a marketing authorization. The statement in relation to its licence was therefore inaccurate, and a breach of the Code was ruled. In addition, the article promoted a medicine prior to the grant of a marketing authorization and the Panel ruled a breach of the Code. As linagliptin did not have a marketing authorization, and therefore did not have a summary of product characteristics (SPC) at the time of publication, the Panel did not consider that the article promoted the medicine outwith the terms of its marketing authorization or inconsistently with its SPC, and ruled no breach of the Code.

On the evidence before it, the Panel did not consider that linagliptin represented a new class of DPP-4 inhibitors. The title of the article implied that the medicine had some special merit, which could not be substantiated, and the Panel ruled breaches of the Code.

The article made it clear that there were currently no head-to-head trials of linagliptin with other DPP-4 inhibitors. The Panel did not consider that the article made misleading comparisons of the efficacy of linagliptin and other DPP-4 inhibitors as alleged and ruled no breach of the Code.

The Panel noted that the article stated that as linagliptin did not interfere with CYP450 it was 'safer to use' concomitantly with certain medications than saxagliptin. Given that there was no head-to-head trial of linagliptin and saxagliptin, the Panel considered that this claim did not reflect available evidence and was not capable of substantiation by clinical experience, and ruled a breach of the Code.

The Panel noted the complainant's comments in relation to the effect on beta-cell function of linagliptin and renal acceptability of the medicine. The Panel did not know whether any of these claims were correct. The Panel noted that the complainant bore the burden of proof. The Panel also noted its comment above that the company was responsible for the article. The Panel considered that as the product did not have a marketing authorization at the time the article was published, its ruling above of a breach of the Code covered these allegations.

With regard to the allegation that the information about possible cost of linagliptin compared with other DPP-4 inhibitors was not factual and potentially misled in relation to the cost-efficacy of the medicine, the Panel noted that the complainant had not explained why the claim at issue was inaccurate. There was no actual or implied cost-efficacy claim. No breach of the Code was ruled. This ruling was unsuccessfully appealed by the complainant.

The Panel considered that Boehringer Ingelheim would have been aware at the outset of the promotional content of the article. For the company to consider it anything other than a promotional item demonstrated a serious lack of understanding of the Code. High standards had not been maintained and ruled a breach of the Code. The Panel considered that Boehringer Ingelheim's involvement with the publication brought discredit upon and reduced confidence in the pharmaceutical industry, and ruled a breach of Clause 2.

In relation to Lilly's involvement with, and responsibility for, the article, the Panel noted that at the time the content of the article was agreed, Lilly and Boehringer Ingelheim had not formed a co-marketing alliance. The proposal for the article in question was sent only to Boehringer Ingelheim and only Boehringer Ingelheim was mentioned in the title of the proposal. Lilly was not aware of the article until it was contacted by Boehringer Ingelheim. Given the exceptional circumstances the Panel did not consider that Lilly was responsible for the article at issue, and ruled no breach of the Code.

A general practitioner complained about an article on linagliptin published in Future Prescriber.

The article 'Linagliptin: new class of DPP-4 [dipeptidyl peptidase-4] inhibitor in the treatment of T2DM [type 2 diabetes mellitus]' was written by two diabetes and endocrinology physicians. A declaration of the authors' interests was given at the end of the article. The final paragraph, which followed the list of references, stated 'Placement of this article has been funded by Boehringer

Ingelheim and Lilly. The content has been independently commissioned by Future Prescriber and has been checked by Boehringer Ingelheim and Lilly for factual accuracy only. Editorial control of this article remains with Future Prescriber'.

COMPLAINT

The complainant stated that the article represented the exaggerated, misleading and disguised promotion of linagliptin before a UK marketing authorization for the product had been granted. The companies were directly responsible for this given that firstly they had funded development of this article, secondly they had reviewed the article for factual accuracy (which evidently was less than rigorous) and finally the authors (both from the same hospital department) had previously received support from the companies which strongly suggested that their views and opinions were likely to be known by both the companies and that they were likely to have been involved in their selection as authors and briefing.

It was stated that these companies had no editorial control but the complainant submitted that they had had an opportunity and responsibility to correct the following misleading, unsubstantiated and factually incorrect information in an article sponsored by them; which they failed to do.

The complainant noted that the article stated that linagliptin was now approved and due to launch in the UK. Most clinicians would reasonably infer that this meant that the medicine had obtained a marketing authorization from the European Commission (EC) before the article was published; this was not so. To date linagliptin had only received a positive opinion from the European Medicines Agency (EMA) which did not equate to the approval of linagliptin in the European Union as stated in the article. These statements were not only factually inaccurate but promoted the availability of linagliptin in the UK prior to full and final regulatory approval.

The complainant alleged that the title of the article 'Linagliptin: new class of DPP-4 inhibitor in the treatment of T2DM', was misleading and exaggerated. DPP-4 inhibitors belonged to a class of incretin-based therapies and the complainant knew of no other widely recognised or accepted sub-class within this that was clinically relevant. Linagliptin did not represent a new class of treatment for type 2 diabetes. To do so suggested an unqualified and unsubstantiated superiority over currently licenced DPP-4 inhibitors, comparisons with which were made throughout the article. If this were truly a new class of treatment then the complainant wondered why the authors cited the National Institute for Health and Clinical Excellence (NICE) guidelines which did not differentiate between different DPP-4 inhibitors based on sub-class. The complainant alleged that this was clearly a contrived marketing message used to promote linagliptin and noted that even the authors struggled to find any real basis to differentiate linagliptin on the basis of class given that, throughout, they referred to linagliptin as a DPP-4 inhibitor. Indeed, in the conclusions the authors explicitly stated that linagliptin had potential advantages over others in the same class. The only fact that was accurate was that linagliptin was a new DPP-4.

The complainant was surprised that, following the factual accuracy check undertaken by the sponsors, the article was permitted to misleadingly elaborate various comparisons of the safety and efficacy of linagliptin with some of the other DPP-4s mentioned. The complainant asked if it was acceptable or factually accurate to compare the maximal efficacy and potency of linagliptin with other DPP-4 inhibitors or claim that, in relation to use with concomitant medicines, linagliptin was safer than saxagliptin; especially given that there were no head-to-head data with other DPP-4 inhibitors to substantiate this.

The complainant alleged that the article was also misleading and inaccurate when it claimed that linagliptin, unlike other unspecified oral antidiabetic medicines, might have a positive and long enduring effect on beta-cell function and therefore glycaemic control; this was not a fact nor could it be substantiated. The claim that linagliptin had the potential to modify and delay the progression of type 2 diabetes was simply fiction as opposed to fact. Editorial control or not, it was clear that the sponsors had not exercised the necessary diligence in their review of the article.

The complainant stated that an unbalanced and distorted promotional message was also elaborated with regard to the important issue of renal acceptability. As no summary of product characteristics (SPC) or specific licence for use of linagliptin in patients with renal impairment was currently available, it was remarkable that the companies considered it was accurate to promote the renal profile of linagliptin by comparing it to the licensed renal indication for saxagliptin and suggesting that the need to reduce the dosage of saxagliptin in moderate to severe renal disease somehow rendered it inferior to linagliptin. Saxagliptin was currently the only DPP-4 inhibitor with a UK licence for use in moderate/severe renal impairment.

The complainant alleged that in the absence of specific details, it was incredible that the companies permitted the discussion of the possible cost of linagliptin compared with other DPP-4 inhibitors. This was not factual information and potentially misled about the cost-efficacy of this medicine.

The complainant alleged that the decision to fund the development of this article and the evident lack of proper scrutiny of the facts and accuracy of the contents suggested that these companies were keen to promote linagliptin prior to licence and inappropriately steal a competitive advantage over medicines such as saxagliptin.

When writing to Boehringer Ingelheim and Lilly, the Authority asked each to respond in relation to Clauses 2, 3.1, 3.2, 7.2, 7.4, 7.9, 7.10, 9.1, 9.10 and 12.1 of the Code.

RESPONSE

Case AUTH/2424/8/11

Boehringer Ingelheim submitted that in November 2010, the publisher of the article made a proposal to the company for the purchase of a quantity of reprints of four articles to be published in future editions of Future Prescriber. The publisher was to independently commission the articles, determine the outline for their content, select and pay the authors and then publish the article. A copy of the proposal from the publisher was provided.

Boehringer Ingelheim submitted that the primary purpose of the proposal document was to allow it to determine, in advance of the articles being written, whether it would like to pre-pay for the advance purchase of a number of reprints of the four articles. Boehringer Ingelheim provided details of the estimated and actual cost of 2000 reprints of the article in question. The company paid for the reprints before the article was written. No formal, written agreement was entered into for this transaction beyond an invoice from the publisher and a purchase order (from Boehringer Ingelheim), copies of which were provided.

Out of courtesy, the articles, including the one in question, were to be sent to Boehringer Ingelheim for a check of factual accuracy only, and as this was an independently authored piece, commissioned by the publisher, the decision to incorporate any feedback from Boehringer Ingelheim regarding changes to the article was at the discretion of the authors and the publisher.

On 5 July, the article in question was sent to Boehringer Ingelheim for a check of factual accuracy. By this time Boehringer Ingelheim and Lilly had formed an alliance in the diabetes arena. Lilly had no knowledge of, or part in, either the commissioning of the article, its review or of the arrangements with Boehringer Ingelheim for advance purchase of the reprints; these arrangements pre-dated the alliance.

On 15 July, Boehringer Ingelheim identified that the article, for which a factual accuracy check was requested, was not fit for purpose in that it contained multiple factual inaccuracies and breaches of the Code, and inaccurately described Lilly's involvement. Furthermore, Boehringer Ingelheim submitted that the article did not match the description contained in the proposal for which 2,000 reprints had been pre-purchased. For all these reasons Boehringer Ingelheim informed the publisher on 15 July that it did not want the article published (Boehringer Ingelheim understood that this was in advance of the date on which the issue of the journal containing the article went to press). Contrary to Boehringer Ingelheim's wishes, and in the full knowledge of Boehringer Ingelheim's concerns, the publisher sent the article to press and consequently it appeared in the print edition of Future Prescriber. At this point, Boehringer Ingelheim told Lilly about the article and its concerns. On the 18 July, and in response to the concerns raised on 15 July, the publisher wrote to Boehringer Ingelheim and restated its position that the article was independently commissioned by the editors of Future Prescriber, they had independently determined the outline and authorship of the article and that the responsibility for incorporation of any changes requested by Boehringer Ingelheim lay with the publisher.

On 4 August, Boehringer Ingelheim and Lilly informed the publisher about this complaint. Whilst it was not possible to recall the print edition of the journal, the companies asked the publisher to remove the article from the online version of Future Prescriber, which had not yet been published. Boehringer Ingelheim and Lilly had since been reassured by the publisher that the article would not appear in the online version of the journal.

Boehringer Ingelheim stated that linagliptin had not yet received a marketing authorization, although it had received positive opinion from the Committee of Medicinal Products for Human Use (CHMP) of the EMA. A decision from the EC was expected in early September.

In summary, Boehringer Ingelheim submitted that whilst the article failed to comply with the Code, it reassured the Authority that it took appropriate (if ultimately unsuccessful) steps to stop the article being published and, once published, against its wishes, had taken active steps to limit its circulation. Boehringer Ingelheim's only role was to pre-pay for a quantity of reprints of an article that when independently commissioned and written, and on publication did not match the description that Boehringer Ingelheim was given and on which it based its purchasing decision. Boehringer Ingelheim therefore maintained that it had not breached the Code.

In response to a request for further information regarding the substantive issues raised by the complainant and the clauses cited by the Authority, Boehringer Ingelheim strongly denied any breach of the Code as a result of any act or omission on its part. Boehringer Ingelheim submitted that it was clear that the article had been published against its wishes. At that stage the article had not been certified by Boehringer Ingelheim as numerous changes were required for it to comply with the Code. Boehringer Ingelheim submitted it was extremely disappointed that this situation had arisen and had addressed the issue with the publisher. Boehringer Ingelheim believed strongly in its internal approval processes and was committed to maintaining high standards and abiding by the Code at all times. Boehringer Ingelheim referred to this paragraph in response to

the Authority's request for it to consider the requirements of Clauses 3.1, 3.2, 7.2, 7.4, 7.9, 7.10 and 12.1.

Boehringer Ingelheim refuted the allegation of a breach of Clause 9.10. On page 5 of the article it was stated: 'Placement of this article has been funded by Boehringer Ingelheim and Lilly. The content has been independently commissioned by Future Prescriber and has been checked by Boehringer Ingelheim and Lilly for factual accuracy only…'. Boehringer Ingelheim submitted that this statement was incorrect. It did not place this article, it had only pre-paid for reprints of an article that was 'sold' to the company as a disease awareness piece, which when seen clearly was not, and this was why Boehringer Ingelheim tried to stop it being published.

Boehringer Ingelheim strongly refuted the allegation of a breach of Clause 9.1. The company submitted that it had clearly outlined above the sequence of events that led to the article being published. The company also submitted that it was clear that it had informed the publisher that the article was not approved for publication since numerous changes were required. It therefore knew that the article did not comply with the Code and at this stage it had not been certified by Boehringer Ingelheim. However, despite this the article was still published by the publisher against Boehringer Ingelheim's explicit wishes. The company submitted that once it knew that the article had been circulated it took significant steps to stop the publication and significant steps to limit its circulation. The company therefore believed that it had maintained high standards at all times and was not in breach Clause 9.1.

For the reasons stated above, Boehringer Ingelheim also strongly refuted the allegation of breach of Clause 2.

Case AUTH/2425/8/11

Lilly noted that in January 2011 it entered into a worldwide alliance with Boehringer Ingelheim for the development and marketing of diabetes medicines. Lilly understood that the article in question was commissioned by Boehringer Ingelheim before the date of the alliance. Lilly had no involvement in the article and was unaware of either it or the arrangements for its publication until it was published in Future Prescriber.

Lilly submitted that the statement at the end of the article regarding its involvement in funding and checking the article for factual accuracy was incorrect and had been included without its approval and/or consent. Lilly stated that it would take the publisher to task over its unauthorised reference to its involvement. Lilly denied a breach of the Code.

Following a request for further information, Lilly submitted that it had not been involved in either commissioning the original article (which occurred in November 2010 prior to the formation of the alliance with Boehringer Ingelheim) nor the review or approval of it. Boehringer Ingelheim paid for the article with no contribution or knowledge of Lilly. Consequently, Lilly did not consider that it was in breach of the Code.

Lilly submitted that it agreed with Boehringer Ingelheim's response. In particular, Lilly noted that the reference to it having had no knowledge of, or part in, either the commissioning of the article, its review, nor the arrangements between Future Prescriber and Boehringer Ingelheim for the advanced purchase of reprints (arrangements which predated Lilly's alliance with Boehringer Ingelheim) was correct and provided evidence that the activity proceeded with no involvement from Lilly.

Lilly submitted that an arrangement for joint approval of alliance materials had been in place since February 2011. The core teams involved in approval for both Boehringer Ingelheim and Lilly were trained in May 2011. The standard operating procedure was formally approved by both companys' senior management and became effective in August 2011.

Lilly noted that the publisher had accepted responsibility for publication of the article in its letter dated 18 July, submitted to the Authority by Boehringer Ingelheim. Boehringer Ingelheim clearly stated that the article was sent to it for a factual accuracy check; no mention was made that Lilly was included and indeed Lilly was not aware of any communication between Boehringer Ingelheim and the publisher concerning the article. As the declaration statement on the article incorrectly referred to Lilly, the publisher had subsequently agreed to publish a correction statement in the next issue of the journal to state that Lilly had no involvement of any sort in the article.

PANEL RULING

Case AUTH/2424/8/11

The Panel noted that it was acceptable for companies to sponsor material. It had previously been decided that the content would be subject to the Code if it was promotional in nature or if the company had used the material for a promotional purpose. Even if neither of these applied, the company would be liable if it had been able to influence the content of the material in a manner favourable to its own interests. It was possible for a company to sponsor material which mentioned its own products and not be liable under the Code for its contents, but only if it had been a strictly arm's length arrangement with no input by the company and no use by the company of the material for promotional purposes.

The Panel noted that the proposal submitted to Boehringer Ingelheim by the publisher was entitled 'Proposal for Boehringer Ingelheim in support of

[Trajenta]. It stated that 'As part of the managed entry programme, appropriate messages must be communicated to healthcare payers in order to prepare the market for the launch of [Trajenta]', and that 'prescribers and payers…..will need to be informed about the unique advantages of [Trajenta]'. It proposed the development of a pair of complementary articles in Future Prescriber to 'support the product'. These would then be followed at launch with a pair of supplements in different journals aimed at payers and prescribers.

The proposal for the article in question was to 'look at the current and future treatment options with particular focus on the DPP4 class and forthcoming products. As the launch of [Trajenta] is likely to be approaching at this point we can include more data on [Trajenta] in this article as it will soon be a licensed option'. The proposal also stated that the article would be independently commissioned, peer reviewed and published within the main pages of the journal. There would be no input from the company other than for medical accuracy. Reprints (2000) would be made available following publication. The Panel noted that minutes submitted by Boehringer Ingelheim for a meeting it had with the publishers of the article and Lilly once the complaint had been received stated that the article format had been agreed as appropriate between the publishers and Boehringer Ingelheim within the timelines of the anticipated launch of Trajenta. The minutes also stated that the agreement with the publisher was that it would take all responsibility for generation of the article, choosing of authors (although it could request input from Boehringer Ingelheim, as it had done in relation to the article in question, but the publishers had made the final choice), managing the writing and review process and publication of the final article.

The Panel disagreed with Boehringer Ingelheim's statement that the article did not match the description given in the proposal on which Boehringer Ingelheim based its decision to purchase reprints, nor did it agree that the article was 'sold' to the company as a disease awareness piece. The Panel considered that it was clear from the proposal that the article would support Trajenta, and that Boehringer Ingelheim would have known this at the outset.

It appeared that although Boehringer Ingelheim did not pay for the article *per se*, it in effect commissioned it through an agreement to pay for 2,000 reprints. The article was a result of a business proposal between the publishers and Boehringer Ingelheim; it would not have been written without the company's agreement to purchase reprints in advance. The Panel considered that Boehringer Ingelheim was inextricably linked to the production of the article, there was no strictly arms length arrangement and in that regard the company was responsible under the Code for the content.

Turning to the article itself, the Panel noted that on the first page, under the heading, appeared the names and affiliations of the authors. The only mention of Boehringer Ingelheim was at the end of the article, after citation of all the references. The Panel considered that the article did not clearly indicate the involvement of the company, and ruled a breach of Clause 9.10. As the content was promotional, the Panel considered that it was disguised in that regard and ruled a breach of Clause 12.1.

The Panel noted that the article stated that linagliptin was approved in the UK and was 'due to launch here soon'. When the article was published, the product had not received a marketing authorization. The statement in relation to its licence was therefore inaccurate, and a breach of Clause 7.2 was ruled. In addition, the article promoted a medicine prior to the grant of a marketing authorization that permitted its sale or supply, and the Panel ruled a breach of Clause 3.1. As linagliptin did not have a marketing authorization, and therefore did not have an SPC at the time of publication, the Panel did not consider that the article promoted the medicine outwith the terms of its marketing authorization or inconsistently with its SPC, and ruled no breach of Clause 3.2.

The Panel noted that the article title was 'Linagliptin: new class of DPP-4 inhibitor in the treatment of T2DM' and the content referred to the medicine belonging to a 'new chemical class of xanthine-based DPP-4 inhibitors'. On the evidence before it, the Panel did not consider that linagliptin represented a new class of DPP-4 inhibitors. The statement implied that the medicine had some special merit, which could not be substantiated, and the Panel ruled a breach of Clauses 7.10 and 7.4.

The article detailed a number of placebo-controlled trials using linagliptin monotherapy or combination therapy with other oral antidiabetic agents. It made it clear that there were currently no head-to-head trials of linagliptin with other DPP-4 inhibitors. The Panel did not consider that the article made misleading comparisons of efficacy of linagliptin and other DPP-4 inhibitors as alleged and ruled no breach of Clause 7.2 in that regard.

The Panel noted that the article stated linagliptin did not interfere with CYP450 and so was 'unlikely to affect the pharmacokinetics of agents that are metabolized by this system'. It then went on to say that as a result of this, linagliptin was 'safer to use' concomitantly with medications such as rifampicin, ketoconazole or diltiazem than saxagliptin. Given that there was no head-to-head trial of linagliptin and saxagliptin, the Panel considered that this claim about the medicines comparative safety did not reflect available evidence and was not capable of substantiation by clinical experience, and ruled a breach of Clause 7.9.

The Panel noted the complainant's comments in relation to reference in the article to the effect on beta-cell function of linagliptin and renal acceptability of the medicine. The article stated that adequate DPP-4 inhibition by linagliptin offered increased availability of GLP-1 endogenously, which in turn stimulated the proliferation and differentiation of beta-cells and hence improved markers of beta-cell function. It also stated that, unlike treatment with other oral hypoglycaemic therapies, which progressively lost glycaemic control over time, linagliptin might have the desired effect of glycaemic durability, as its DPP-4 inhibitory action was glucose dependent. In relation to renal impairment, the article stated that in a phase 3 study, 50% of patients receiving linagliptin had moderate to severe renal function, yet the trough linagliptin concentration in the treatment group was similar to those with normal renal function. The article noted that this implied dose adjustment might not be required in renally impaired patients. The Panel did not know whether any of these claims were correct. The Panel noted that the complainant bore the burden of proof. The Panel also noted its comment above that the company was responsible for the article. The Panel considered that as the product did not have a marketing authorisation at the time the article was published, its ruling of a breach of Clause 3.1 above covered these allegations.

The Panel noted the complainant's allegation that the information about possible cost of linagliptin compared with other DPP-4 inhibitors was not factual and potentially misled in relation to the cost-efficacy of the medicine. The article stated that the cost of linagliptin was anticipated to be similar to the other already marketed DPP-4 inhibitors ie around £32 per month. The Panel noted that the complainant bore the burden of proof. The Panel noted that the complainant had not explained why the claim at issue was inaccurate. There was no actual or implied cost-efficacy claim. No breach of Clause 7.2 was ruled. This ruling was appealed by the complainant.

Taking all the circumstances in to account, the Panel considered that Boehringer Ingelheim would have been aware at the outset of the promotional content of the article. For the company to consider it anything other than a promotional item demonstrated a serious lack of understanding of the Code. The Panel considered that high standards had not been maintained and ruled a breach of Clause 9.1 in that regard. The Panel was concerned that the company had entered into the agreement with the publisher given that the proposal described promotional articles prior to the grant of the product's marketing authorization. The Panel noted that such activity was one of the examples given in the Code as likely to lead to a breach of Clause 2. The Panel noted that Boehringer Ingelheim's submission that it had tried to prevent publication, but considered that Boehringer Ingelheim's involvement with the publication brought discredit upon and reduced confidence in the pharmaceutical industry, and ruled a breach of Clause 2.

APPEAL BY THE COMPLAINANT

The complainant stated that the article extensively promoted the efficacy and other benefits of linagliptin in direct comparison to other DPP-4 inhibitors and then referred to the (unconfirmed) cost for linagliptin. In this context the statement that the anticipated cost of linagliptin was likely to be similar to the other already marketed DPP-4 inhibitors was a direct claim of the similar or comparable cost (and cost-efficacy) of linagliptin to other DPP-4 inhibitors. The complainant appealed the Panel's ruling of no breach of Clause 7.2.

COMMENTS FROM BOEHRINGER INGELHEIM

Boehringer Ingelheim did not comment upon the reasons for the appeal and had nothing further to add to its response to the Panel.

FINAL COMMENTS FROM THE COMPLAINANT

The complainant had no comment on Boehringer Ingelheim's response.

APPEAL BOARD RULING

The Appeal Board noted that the article had been published against Boehringer Ingelheim's wishes. The company had not provided any information for inclusion in the article. Boehringer Ingelheim submitted at the appeal hearing that the price range for linagliptin was not in the public domain when the article was published. It was not known what information the authors had relied upon when drafting the claim at issue. In the event it had turned out that the cost quoted in the article was similar to the actual cost of the medicine once launched and similar to the other DPP-4 inhibitors already marketed.

On the narrow grounds of the complaint the Appeal Board considered that when the claim at issue, 'The cost of linagliptin is anticipated to be similar to the other already marketed DPP-4 inhibitors (ie around £32 per month)', was made it was not in itself misleading as alleged. Further, the actual cost of the product did not, in the circumstances, render the claim misleading. The Appeal Board upheld the Panel's ruling of no breach of Clause 7.2. The appeal on this point was thus unsuccessful.

Case AUTH/2425/8/11

The Panel noted that at the time the content of the article was agreed, Lilly and Boehringer Ingelheim had not formed an alliance for the promotion of Trajenta. The proposal for the article in question was sent only to Boehringer Ingelheim and only Boehringer Ingelheim was mentioned in the title of the proposal. The Panel noted the submission from both companies that Lilly was not aware of the

article until it was contacted by Boehringer Ingelheim in July. Lilly had not contributed to the payment made to the publishers and the article was not sent to Lilly for it to check the factual accuracy of the content. The Panel noted that an arrangement for joint approval of materials had been in place since February 2011. The approval workflow referred to pre-launch materials. However, given the exceptional circumstances and irrespective of the fact that Lilly's name appeared on the material, the Panel did not consider that Lilly was responsible for the article at issue, and ruled no breach of Clauses 2, 3.1, 3.2, 7.2, 7.4, 7.9, 9.1, 9.10 and 12.1 of the Code.

Complaint received **3 August 2011**

Case AUTH/2424/8/11 completed **16 November 2011**

Case AUTH/2425/8/11 completed **4 October 2011**

MEMBERS OF THE PUBLIC v ASTRAZENECA and BRISTOL-MYERS SQUIBB

Onglyza advertisement in the Health Service Journal

Two complaints were received about an advertisement in the Health Service Journal (HSJ) for Onglyza (saxagliptin), co-marketed by AstraZeneca UK and Bristol-Myers Squibb Pharmaceuticals. Onglyza was an add-on therapy for type 2 diabetics not controlled on metformin or a sulphonylurea alone.

In Cases AUTH/2426/8/11 and AUTH/2427/8/11 the complainant queried whether the placement of the advertisement was appropriate given that the HSJ was read by NHS managers in all roles and levels of seniority, and also by members of the public.

In Cases AUTH/2728/8/11 and AUTH/2429/8/11 the complainant stated that given its technical content, the advertisement should have appeared in medical and clinical publications only. The complainant queried whether it should have been placed in the HSJ.

The detailed response from AstraZeneca and Bristol-Myers Squibb is given below.

The Panel noted that the Code applied to the promotion of medicines to health professionals and to appropriate administrative staff. It required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. Promotional material should be tailored to the audience to whom it was directed.

The Panel considered that the HSJ was a specialist professional title and was not aimed at the general public. The Panel did not accept that the advertisement was an advertisement to the public as alleged and considered that the publication was an acceptable vehicle for the advertisement of prescription only medicines. No breach of the Code was ruled.

The Panel noted that the journal was mainly read by administrative and general management personnel and by only a relatively small percentage of clinicians. The Panel noted that the title of the advertisement referred to Onglyza being 'an add-on alternative for your patients ...'. The Panel considered that the advertisement contained a considerable amount of clinical information and noted that only the acquisition cost of Onglyza compared with other treatments was stated. The advertisement, however, referred to the requirement for an initial assessment of renal function in patients with renal disease, together with periodical assessment thereafter, but the cost of this monitoring was not stated. The Panel thus did not consider that the advertisement included all the cost information that a manager would need.

The Panel considered that the reference to 'your patients' in the title, together with the content of the advertisement, was such that it was aimed at clinicians. It had not been tailored to the main audience of the HSJ. A breach of the Code was ruled which was appealed by AstraZeneca and Bristol-Myers Squibb.

The Appeal Board noted the companies' submission that the advertisement was aimed at an audience of those responsible for budgetary decisions which included a wide variety of management roles.

Although the Appeal Board considered that the heading might be more suited to clinicians it did not consider that the term 'your patients' was necessarily only appropriate in material aimed at clinicians. The content of the advertisement was broad and included information on efficacy, side effects, tolerability and acquisition costs, topics which would be of interest to the budgetary impact/payer audience that read the HSJ. The Appeal Board noted the companies' submission that the treatment costs, above and beyond acquisition costs, for all the other medicines referred to were broadly similar.

The Appeal Board was satisfied that the advertisement was sufficiently tailored to a significant proportion of the HSJ audience and in that regard the audience could reasonably be assumed to have an interest in it. The Appeal Board ruled no breach of the Code. The appeal was thus successful.

Two complaints were received about a full page advertisement (ref 422UK11PM170/CZ006148-ONGL) for Onglyza (saxagliptin), co-marketed by AstraZeneca UK Limited and Bristol-Myers Squibb Pharmaceuticals Limited. The advertisement, which took the form of an advertorial, had been published in the Health Service Journal 4 August 2011. Onglyza was an add-on therapy for type 2 diabetics not controlled on metformin or a sulphonylurea alone.

Cases AUTH/2426/8/11 and AUTH/2427/8/11

COMPLAINT

The complainant queried whether the placement of the advertisement was appropriate given that the Health Service Journal was read by NHS managers in all roles and levels of seniority, and also by members of the public.

Cases AUTH/2428/8/11 and AUTH/2429/8/11

COMPLAINT

The complainant considered that the advertisement was a full blown technical advertisement that should appear in medical and clinical publications only. The complainant queried whether the advertisement should have been placed in the Health Service Journal.

When writing to AstraZeneca and Bristol-Myers Squibb, the Authority asked them to consider the requirements of Clauses 11.1 and 22.1.

RESPONSE TO BOTH COMPLAINTS

Bristol-Myers Squibb responded on behalf of both companies and submitted that the Health Service Journal was a leading provider of NHS and private health care news and policy information which was only available to subscribers and not promoted to the public. Typical subscribers included primary and secondary care doctors, nurses, pharmacists, primary care trust (PCT) commissioners, medical directors and finance directors. Both companies had a policy to only advertise prescription only medicines in journals that were distributed to health professionals and appropriate administrative staff and therefore they believed this was an appropriate journal in which to place a payer orientated Onglyza advertisement.

The advertisement itself was designed specifically for that audience. In addition to describing where saxagliptin might be appropriately used and its safety and tolerability profile, the advertisement also compared the acquisition costs of Onglyza with other dipeptidyl peptidase-4 (DPP-4) inhibitors and pioglitazone. The companies considered that this information was appropriate to the Health Service Journal readership. The advertisement was certified specifically for inclusion in the Health Service Journal, with knowledge of, and consideration for, the potential audience, as required by the Code.

Bristol-Myers Squibb and AstraZeneca maintained that there had been no breach of Clauses 11.1 and 22.1 and that the advertisement complied with the letter and spirit of the Code.

PANEL RULING

The Panel noted that Clause 1.1 stated that the Code applied to the promotion of medicines to members of the United Kingdom health professions and to appropriate administrative staff. Clause 11.1 required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. The supplementary information to Clause 11.1 stated that promotional material should be tailored to the audience to whom it was directed.

The Panel considered that the Health Service Journal was a specialist professional title and was not aimed at the general public. The Panel considered that the key factor was to whom the publication was aimed at rather than whether it could be purchased by the public. The Panel did not accept that the advertisement was an advertisement to the public as alleged and considered that the publication was an acceptable vehicle for the advertisement of prescription only medicines. The Panel therefore ruled no breach of Clause 22.1.

The Panel then considered whether the content of the advertisement was suitable for the readership of the journal. The audience profile breakdown submitted by Bristol-Myers Squibb and AstraZeneca showed that the journal was mainly read by administrative and general management personnel and by only a relatively small percentage of clinicians.

The Panel noted that the title of the advertisement referred to Onglyza being 'an add-on alternative for your patients …'. The Panel considered that the advertisement contained a considerable amount of clinical information and noted that only the acquisition cost of Onglyza compared with other treatments was stated. The advertisement, however, referred to the requirement for an initial assessment of renal function in patients with renal disease, together with periodical assessment thereafter, but the cost of this monitoring was not stated. The Panel thus did not consider that the advertisement included all the cost information that a manager would need.

The Panel considered that the reference to 'your patients' in the title, together with the content of the advertisement, was such that it was aimed at clinicians. It had not been tailored to the main audience of the Health Service Journal. The Panel therefore ruled a breach of Clause 11.1. This ruling was appealed by AstraZeneca and Bristol-Myers Squibb.

APPEAL BY ASTRAZENECA AND BRISTOL-MYERS SQUIBB

Bristol-Myers Squibb appealed on behalf of both companies and submitted that the basis of the ruling of a breach of Clause 11.1 was the imbalance between clinical and cost information and as such, the Panel considered it was not suitable for those who read the Health Service Journal. The Panel stated that '... the journal was mainly read by administrative and general management personnel

and by only a relatively small percentage of clinicians'. Within the current NHS environment, budgetary decisions were made by a wide number of management roles across the varied NHS structures including, *inter alia*, commissioners, primary care personnel and acute trust staff. In addition, many of these management roles were occupied by clinically qualified practitioners. In arriving at local formulary/protocol decisions the primary consideration was the clinical merit of the intervention and thereafter, where this had been met, the economic impact of the treatment. Several drug and therapeutics committees stated on their websites their role in assessing both the efficacy and safety of new medicines, as well the financial implications of their use. Furthermore, an advisory board which included members of NHS management - a director of finance, head of finance and commissioning performance, business services manager, associate director of primary care and pharmacists - advised that such personnel needed information on efficacy, safety and cost of a medicine to make a market access decision.

The advertisement was orientated to payers and provided appropriate clinical information to meet their needs ie an appropriate positioning of the medicine (suitable patients), a few facts that addressed the major safety concerns in this therapy area and a table outlining acquisition costs of the competing options.

The companies noted that the Panel was concerned that the advertisement did not include all of the financial information that a manager would require, in that there was no reference to the cost of renal monitoring. These data were not included as renal monitoring applied to all of the referred treatment options as part of the National Institute for Health and Clinical Excellence (NICE) guideline on the routine management of type 2 diabetics, which stated that a renal assessment should be conducted at least annually. As this cost already existed within the existing care pathway, managers did not require this information when considering alternative therapeutic options for their diabetes patients – the key requirement was acquisition cost, which was included.

With regard to the Panel's comment that the use of 'your patients' indicated that the advertisement was solely directed to clinicians, AstraZeneca and Bristol-Myers Squibb submitted that this interpretation of 'ownership' of patients was too narrow within the context of the NHS; everyone working within a local health economy took responsibility for any patient within their organisation and managers would consider them to be 'their patients' too.

AstraZeneca and Bristol-Myers Squibb submitted that the advertisement had been developed in accordance with the Code. The companies provided a copy of an advisory board report exploring NHS priorities and agendas in diabetes, a supporting letter from an NHS manager from a PCT and examples of other recent advertisements from the Health Service Journal that contained both clinical and payer focus.

COMMENT FROM THE COMPLAINANT IN CASES AUTH/2426/8/11 AND AUTH/2427/8/11

The complainant stated that he sympathized with most of the points raised by the NHS manager but had a different view around perceptions of the composition of the Health Service Journal's readership and as the facts of the journal's readership had already been reviewed in these cases, these differences in perception were moot.

COMMENT FROM THE COMPLAINANT IN CASES AUTH/2428/8/11 AND AUTH/2429/8/11

The complainant stated that the letter from the NHS manager provided by Bristol-Myers Squibb and AstraZeneca was irrelevant to his complaint as the author dealt with how he wished things to be.

The complainant stated that this process was a palaver and that most complaints were company to company and the system was geared to that.

The complaint stated that this case was obvious, the Health Service Journal never carried this type of advertising. The readership profile was available from its marketing department.

The complainant considered that the complaints procedure was designed to put off ordinary complainants, the sanctions were a wet lettuce slap and confirmed his view, whatever the outcome, that self regulation was not in the public interest.

APPEAL BOARD RULING

The Appeal Board noted that Clause 11.1 required that promotional material should only be sent or distributed to those categories of persons whose need for, or interest in, the particular information could reasonably be assumed. The supplementary information to Clause 11.1 stated that promotional material should be tailored to the audience to whom it was directed.

The Appeal Board noted the companies' submission that the advertisement was aimed at an audience of those responsible for budgetary decisions which included a wide variety of management roles.

The Appeal Board noted that the Health Service Journal was a subscription journal with a wide readership. The audience profile data in relation to 'Areas of purchasing responsibility' indicated that 18% of readers had a role in purchasing medicines and 71% had a training, educational or learning responsibility. The job role data indicated 28% of readers were in 'Management and best practice' roles; 26% in 'Policy and politics'; 24% in 'Commissioning'; 19% in 'Primary care' and 17% in 'Acute care'. The majority of subscribers were in a management or senior role.

The Appeal Board noted the companies' submission that although the heading to the advertisement 'Onglyza … is an add-on alternative for your patients with type 2 diabetes not controlled on metformin or a sulphonylurea (SU) alone' had been used for different advertisements in other journals the content of the advertisement at issue was designed specifically for the Health Service Journal audience and had only ever appeared in that journal.

Although the Appeal Board considered that the heading might be more suited to clinicians it did not consider that the term 'your patients' was necessarily only appropriate in material aimed at clinicians. The content of the advertisement was broad and included information on efficacy, side effects, tolerability and acquisition costs and in the Appeal Board's view these topics would be of interest to the budgetary impact/payer audience that read the Health Service Journal. The Appeal Board noted the companies' submission that the treatment costs, above and beyond acquisition costs, for all the other medicines referred to were broadly similar.

The Appeal Board was satisfied that the advertisement was sufficiently tailored to a significant proportion of the Health Service Journal audience and in that regard the audience could reasonably be assumed to have an interest in it. The Appeal Board ruled no breach of Clause 11.1. The appeal was thus successful.

Complaint received Case AUTH/2426/8/11 and AUTH/2427/8/11 **8 August 2011**

Complaint received Case AUTH/2428/8/11 and AUTH/2429/8/11 **9 August 2011**

Cases completed **16 November 2011**

CASE AUTH/2436/9/11

GENZYME v SHIRE

VPRIV website

Genzyme complained about claims on the VPRIV (velaglucerase alfa) website, created by Shire. Genzyme further alleged that the health professionals' part of the website was easily accessible, allowing the public to read promotional claims. Genzyme marketed Cerezyme (imiglucerase). VPRIV and Cerezyme were both enzyme replacement therapies indicated in patients with Gaucher disease.

The detailed response from Shire is given below.

To the right of a table of data comparing the efficacy of Cerezyme and VPRIV was a claim that VPRIV was 'at least as effective as' Cerezyme. Genzyme submitted that 'at least as effective as' did not properly describe the results of a non-inferiority study and alleged that the claim was unbalanced, misleading and exaggerated.

The Panel noted that the data from the non-inferiority study (reported in the summary of product characteristics (SPC)) showed that the efficacy of VPRIV, measured by the increase in haemoglobin concentration, was clinically and statistically non-inferior to imiglucerase. The SPC also noted no statistically significant differences between the two medicines in terms of platelet counts and liver and spleen volumes.

The Panel noted that non-inferiority studies showed that even if one product was worse than the other it was only worse within clinically unimportant limits. The phrase 'at least as effective as' not only implied equivalence but also possible superiority, which was misleading and did not reflect the available evidence. Breaches of the Code were ruled.

With regard to the manufacture of VPRIV, Genzyme alleged that a claim that the process did not require gene manipulation was incorrect because Shire's technology introduced a gene activator sequence adjacent to a gene which was clearly gene manipulation.

The Panel noted that the claim was on the health professionals' part of the website. In the Panel's view, the manufacturing process of enzymes such as VPRIV was complicated and some health professionals would not have a deep understanding of the technical issues involved. VPRIV was produced by gene activation technology in a human cell line.

The claim at issue stated that the manufacture of VPRIV 'does not require gene manipulation' and in that regard the Panel noted that to some readers 'manipulation' would mean to manage, influence or in some other way change. In the Panel's view activating a gene would influence or change it in some way. The Panel considered that the claim was misleading and a breach of the Code was ruled.

Genzyme alleged that the claim that Shire's human genetic therapies, were 'free of animal components, thus minimising the risk of viral contamination' was irrelevant to Shire's immortalised human malignant cells and did not apply to human viruses which were most relevant to a human medicine. It was therefore incomplete, unbalanced and inaccurate.

The Panel noted that according to Shire, in 2009 the availability of Genzyme's product had been significantly adversely affected by a viral contamination; there were still some ongoing supply issues. The Panel further noted that in inter-company dialogue Shire stated that it had not claimed that the use of human cell lines minimised viral contaminants. It was the fact that no animal component was introduced into the bioreactor that minimised the risk of viral contamination, not that the cell line was a human cell line. Genzyme in response noted that Shire's argument applied to animal viruses but not human viruses and that the use of a human cell line might not reduce the risk of contamination with a human virus. The Panel considered that the claim implied that, in Shire's human genetic therapies, there was a minimal risk of contamination with any virus, animal or human. This was not so. Not introducing animal components in to the manufacturing process had no impact on the risk of contamination with human viruses. The claim was misleading and a breach of the Code was ruled.

Genzyme alleged that the health professionals' part of the website was easily accessible by members of the public in breach of the Code. Whilst patients should have access to information about their disease and treatment, the website allowed easy access to all promotional claims, including those which Genzyme considered to be disparaging, inaccurate and unsubstantiated.

The Panel noted that the Code stated that unless access to promotional material about prescription only medicines was limited to health professionals and appropriate administrative staff, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each

target audience clearly separated and the intended audience identified.

The welcome page of the VPRIV website asked the reader to enter the section of the site that was most relevant to them, by clicking on either 'I am a patient, carer or family member' or 'I am a healthcare professional'. If the reader clicked on the latter, they were asked to reconfirm that they were a health professional. Only by reconfirming their professional status could they access promotional material for VPRIV.

The Panel considered that the section providing promotional information to health professionals was clearly separated from the section containing information for the public, patient, carer or family member, and the intended audience for each section was clear. The Panel did not consider that the promotional material was intended for members of the public. The promotional material on the website in the health professional section did not constitute an advertisement to the public, nor did it encourage a member of the public to ask their health professional to prescribe a prescription only medicine. No breaches of the Code were ruled.

Genzyme Therapeutics Ltd complained about Shire Pharmaceuticals Ltd's promotion of VPRIV (velaglucerase alfa) on the website www.vpriv.co.uk. VPRIV was indicated for long-term enzyme replacement therapy (ERT) in patients with type 1 Gaucher disease. Cerezyme (imiglucerase) (marketed by Genzyme) was indicated for long-term ERT in patients with a confirmed diagnosis of non-neuronopathic (type 1) or chronic neuronopathic (type 3) Gaucher disease who exhibited clinically significant non-neurological manifestations of the disease.

Shire explained that Gaucher disease was an orphan disease (<5 patients per 10,000 population) and there were approximately 240 patients in the UK currently treated with ERT. Access to accurate information was therefore especially vital for patients, patient organisations and general health professionals as well as the specialists in the eight nationally commissioned centres that prescribed for this condition.

Shire stated that for many years Cerezyme had been the only licensed ERT for Gaucher disease. VPRIV had been in clinical development since 2004 and received EU marketing authorization in 2010. The two enzymes were similar but there were some key differences, in particular in the manufacturing process. In 2009 a viral contamination significantly affected worldwide availability of Cerezyme and the resulting challenges to the supply of this product continued to date. In response to this shortage, Shire increased the production of VPRIV and in 2009/10 made it available through an early access programme in many countries including the UK. The planned product launch was also brought forward significantly to ensure that patients who were not able to obtain Cerezyme at the time could continue ERT.

Shire did not consider that the website contained any inaccurate or unsubstantiated claims. However, in an effort to resolve the dispute amicably it had agreed to make changes, but, due to its internal review process, had been unable to agree a timeline with Genzyme. Shire had considered that some of Genzyme's requests for amending the website were unrealistic.

1 Claim 'at least as effective as'

One of the pages of the website featured a table comparing the mean change (increase) in haemoglobin concentration at nine months for imiglucerase vs VPRIV. A bullet point to the right of the table stated that VPRIV was at least as effective as the same dose of imiglucerase.

COMPLAINT

Genzyme submitted that 'at least as effective as' did not properly describe the results of a non-inferiority study which should be 'at least X% effective as' where X% was the calculated lower confidence interval of relative efficacy. Genzyme alleged that the claim was unbalanced, misleading and exaggerated the probable comparative efficacy of VPRIV in breach of Clauses 7.2 and 7.3 of the Code.

RESPONSE

Shire submitted that it was surprised to receive a complaint on this point in light of the data on the website. The table adjacent to the claim at issue contained important, relevant and robust summary statistics, presented for both intention to treat and per protocol populations, that were accurate, fair and objective. Shire stated that the data clearly demonstrated that to a high degree of certainty, VPRIV was at least as good as Cerezyme in the primary end point measure of increasing haemoglobin.

Shire stated that it had designed its non-inferiority study (study 039) with a one-sided 0.025 alpha level, which it submitted was a more conservative approach than the more widely used one-sided 0.05 level typically applied in this setting and further supported the robustness of its conclusion.

Shire stated that including all the statistical information as above, it believed the comparison was valid and in line with Clause 7.3. To support the data from the 039 study, Shire had also included on the same page the top-line results from the 025, 032 and 034 studies, which it submitted supported the efficacy of VPRIV shown in the development programme that included a phase I/II, dose finding and switch study. Copies of these studies were provided.

Shire therefore submitted that the complaint was unfounded. However, in the interests of clarity and to avoid any further difference of opinion, it had prepared a change to the statement.

PANEL RULING

The Panel noted that the claim at issue was referenced to the summary of product characteristics (SPC) for VPRIV. Section 5.1 of the SPC, Pharmacodynamic properties, gave details of, *inter alia*, study 039 which was a nine month randomized, double blinded, non-inferiority, active-comparator (imiglucerase) controlled, parallel-group efficacy study in 34 patients aged 2 years and older who were naïve to ERT. The increase in haemoglobin concentration seen with VPRIV was demonstrated to be clinically and statistically non-inferior to imiglucerase. The SPC also stated that there were no statistically significant differences between VPRIV and imiglucerase in changes in platelet counts and liver and spleen volumes after nine months of VPRIV treatment and in the time to first haemoglobin response (defined as 1g/dl increase from baseline).

The Panel noted that non-inferiority studies showed that even if one product was worse than the other it was only worse within clinically unimportant limits. The phrase 'at least as effective as' not only implied equivalence but also possible superiority, which was misleading. A breach of Clause 7.2 was ruled. The claim did not reflect the available evidence and a breach of Clause 7.3 was ruled.

2 Claim 'does not require gene manipulation'

On a page of the website headed 'About VPRIV' and under a subheading of 'Our manufacturing process' it was stated 'This technology minimizes the introduction of cloning mutations into the gene and does not require gene manipulation, unlike cell lines derived from animals or plants'.

COMPLAINT

Genzyme stated that Shire's technology introduced a gene activator sequence adjacent to a gene which was clearly 'gene manipulation'. Genzyme alleged that the claim was clearly incorrect in breach of Clause 7.2. In addition, the claim disparaged Cerezyme by implication.

RESPONSE

Shire noted that Genzyme accepted that a promoter was not part of the gene, and stated, correctly, that the technique for making VPRIV included placing a gene activator adjacent to the gene.

Shire submitted that there was a clear distinction between the definitions for genome and gene. The Oxford Dictionaries defined gene as the distinct sequence of nucleotides which formed part of a chromosome the order of which determined the order of monomers in a polypeptide, and genome as the complete set of genes or genetic material in a cell or organism. Shire submitted that the promoter sequence was not considered to be part of the gene, but might be a considerable distance away from it. Shire stated that this was absolutely not manipulation of the gene.

Shire stated it was important for readers of the website to be aware of the differences of using a naturally occurring human DNA sequence that coded for the B-glucocerebrosidase (GCR) enzyme, within a human cell expression system (as was the case for VPRIV) and given the spotlight on manufacturing, it considered it was important to be able to differentiate from the manufacturing techniques by which alternative products were made. Shire stated that the patent for Cerezyme clearly described a different method for making a version of GCR which resulted in Cerezyme having one amino acid difference to human GCR.

Shire stated using the gene activation system to make GCR did not require alteration of the nucleotide sequence of the gene and hence it stood by the claim that the production of VPRIV did not require gene manipulation. Additionally, Shire noted that the information on the text on the website did not infer any benefit, but merely stated the difference of its process. Genzyme's claim that there were disparaging implications for its process was incorrect and therefore this was an unfounded allegation.

PANEL RULING

The Panel noted that the claim at issue was on that part of the website intended for health professionals. In the Panel's view, the manufacturing process of enzymes such as VPRIV and Cerezyme were complicated and some health professionals would not have a deep understanding of the technical issues involved. The VPRIV SPC stated that velaglucerase alfa was produced by gene activation technology in a human cell line.

The claim at issue stated that the manufacture of VPRIV 'does not require gene manipulation' and in that regard the Panel noted that to some readers 'manipulation' would mean to manage, influence or in some other way change. In the Panel's view activating a gene would influence or change it in some way. The Panel considered that the claim was misleading and a breach of Clause 7.2 was ruled.

The Panel noted that although Genzyme had also alleged that the claim disparaged Cerezyme by implication, it had not cited Clause 8.1. Paragraph 5.3 of the Constitution and Procedure required companies to state those clauses which are alleged to have been breached. With no allegation of a breach of Clause 8.1, the Panel could not make a ruling on this point.

3 Claim 'Shire HGT's [human genetic therapies] bioreactor cell lines are free of animal components, thus minimising the risk of viral contamination…'

This claim appeared on a page of the website

headed 'About VPRIV' and under a subheading of 'Minimising manufacturing risk'.

COMPLAINT

Genzyme alleged that the claim was somewhat irrelevant to Shire's immortalised human malignant cells and obviously did not apply to human viruses which were most relevant to a human medicine. It was therefore incomplete, unbalanced and inaccurate, and in breach of Clause 7.2. Genzyme also alleged that the claim disparaged its manufacturing methods for Cerezyme by implication.

RESPONSE

Shire was unclear as to why Genzyme had complained about the factual statements Shire made about its own manufacturing process, nor how Genzyme considered the statements referred to its product as, in this text, Shire did not reference any process other than its own and it did not have any depth of knowledge of the manufacturing processes used by Genzyme.

Shire submitted that in order to address questions in the market about whether it could be at risk of viral infection, it had presented basic facts about its manufacturing processes. Shire submitted this was an unfounded allegation.

PANEL RULING

The Panel noted that according to Shire, in 2009 the availability of Genzyme's product had been significantly adversely affected by a viral contamination; there were still some ongoing supply issues. The Panel further noted that in inter-company dialogue Shire stated that it had not claimed that the use of human cell lines minimised viral contaminants. It was the fact that no animal component was introduced into the bioreactor that minimised the risk of viral contamination, not that the cell line was a human cell line. Genzyme in response noted that Shire's argument applied to animal viruses but not human viruses and that the use of a human cell line might not reduce the risk of contamination with a human virus. The Panel considered that the claim implied that, in Shire's human genetic therapies, there was a minimal risk of contamination with any virus, animal or human. This was not so. Not introducing animal components in to the manufacturing process had no impact on the risk of contamination with human viruses. The claim was misleading and a breach of Clause 7.2 was ruled.

The Panel noted that although Genzyme had also alleged that the claim disparaged Cerezyme by implication, it had not cited Clause 8.1. Paragraph 5.3 of the Constitution and Procedure required companies to state those clauses which are alleged to have been breached. With no allegation of a breach of Clause 8.1, the Panel could not make a ruling on this point.

4 Alleged promotion to the public

COMPLAINT

Genzyme noted that the portion of the website purportedly allocated for the use of health professionals was easily accessible by members of the public in breach of Clauses 22.1, 22.2, 24.1 and 24.3. Whilst Genzyme strongly believed that patients should have access to reliable, balanced and clear information about their disease and treatment, the configuration of the website allowed easy access to all promotional claims, including those which Genzyme considered to be disparaging, inaccurate and unsubstantiated.

RESPONSE

Shire submitted that it was particularly dismayed by this complaint and considered that Genzyme was time wasting to take Shire away from its focus of providing effective medicines to patients. Shire stated that the website clearly met the guidance on the use of the Internet as set out in Clause 24.1. The claims at issue above were in the health professional section of the website which Shire submitted was clearly separated from the 'Patient, carer or family member' section at the point of entry into the site. Shire denied a breach of Clause 24.3. Shire stated that the configuration of its website with clearly separated and identified points of access to either the health professional or patient sections was a widely used practice. The website met the requirements of Clause 24 and Shire denied breaches of Clauses 22.1 or 22.2.

Shire provided a copy of a leavepiece that promoted the website to health professionals. The website had never been promoted directly to the public. The patient organisation, The Gauchers Association, of its own volition, had placed a news story about the site on its own website www.gaucher.org.uk/news.php (a screen shot of the relevant section of the patient organisation's website was provided). Shire engaged with The Gaucher Association to review the patient section of the VPRIV website for comments or feedback before launch. Shire submitted that The Gaucher Association pro-actively publicised any information that it considered could be of value to its members.

PANEL RULING

The Panel noted that the supplementary information to Clause 24.1 stated that unless access to promotional material about prescription only medicines was limited to health professionals and appropriate administrative staff, a pharmaceutical company website or a company sponsored website must provide information for the public as well as promotion to health professionals with the sections for each target audience clearly separated and the intended audience identified.

The Panel noted that the welcome page of the VPRIV website asked the reader to enter the section

of the site that was most relevant to them. The options were to click on either 'I am a patient, carer or family member' or 'I am a healthcare professional'. If the reader clicked on the latter, they were taken to a page that stated that information was intended for health professionals only and asked to tick a box to confirm that they were a health professional. If the box was ticked, the reader could access promotional material for VPRIV by clicking a 'Continue' button. If the box was not ticked, the reader could not access promotional material when the 'Continue' button was clicked. The Panel noted that on entering the section for the patient, carer or family member, the first page stated that the website was developed to provide information to the general public, patients and their families, and also to health professionals about velaglucerase alfa.

The Panel noted that the supplementary information to Clause 24.1 referred to material for health professionals and material for the public. It did not mention material for patients that had been prescribed the medicine. The Panel noted that the website was promoted to health professionals only.

The Panel considered that the section providing promotional information to health professionals was clearly separated from the section containing information for the public, patient, carer or family member, and the intended audience for each section was clear. The Panel ruled no breach of Clause 24.1. The Panel did not consider that the promotional material was intended for members of the public and ruled no breach of Clause 24.3. The promotional material on the website in the health professional section did not constitute an advertisement to the public, nor did it encourage a member of the public to ask their health professional to prescribe a prescription only medicine. No breach of Clauses 22.1 and 22.2 was ruled.

Complaint received **22 September 2011**

Case completed **7 November 2011**

GENERAL PRACTITIONER v GRÜNENTHAL

Promotion of Palexia

A general practitioner complained that a four page dosing and titration leavepiece for Palexia SR (tapentadol prolonged release) issued by Grünenthal was misleading with regard to the licensed patient population.

Page 2 was headed 'Palexia SR – Unlock the potential in patients not currently taking strong opioids'. Under a sub-heading of 'Start low, go slow', advice on dosage in patients who were currently not taking strong opioids was given.

The complainant noted that Palexia SR was indicated for the management of adults with severe chronic pain which could be adequately managed only with opioid analgesics.

The complainant submitted that the leavepiece was misleading particularly on the second page where, in his view, it attempted to ask prescribers to prescribe Palexia SR for patients not currently taking strong opioids. This appeared to be outside of the licensed guidance and therefore in breach of the Code in promoting such an indication. The complainant queried why someone would want to take Palexia SR if their pain was adequately controlled by a strong opiate because there appeared to be no discernable advantages.

The detailed response from Grünenthal is given below.

The Panel noted that the leavepiece entitled 'Starting to unlock the potential of Palexia SR (tapentadol prolonged release tablets): Dosing and titration guidance' featured on the bottom left hand corner of the front page a statement about its licensed indication: 'Palexia SR is indicated for the treatment of chronic pain in adults, which can be adequately managed only with opioid analgesics'. Page 2 began with the claim at issue and the prominent heading 'Palexia SR-Unlock the potential in patients not currently taking strong opioids'. Dosage recommendations in patients currently not taking opioid analgesics appeared beneath the subheading 'Start low, go slow'.

According to its summary of product characteristics (SPC), Palexia SR was indicated for the management of severe chronic pain in adults, which could be adequately managed only with opioid analgesics.

The Panel considered that the claim at issue implied that Palexia SR was indicated for use in all patients not currently taking strong opioids and that was not so. Its use was restricted to those patients who could be adequately managed only with opioid analgesics. Neither the claim, nor its immediate visual field nor the text below described the patient population for whom Palexia was indicated. The claim was inconsistent with the SPC and misleading in this regard. The Panel noted that a statement about the licensed indication appeared on the front page of the leavepiece but considered that this did not counter the misleading nature of the claim at issue and thus breaches of the Code were ruled. The Panel considered that this ruling covered the allegation and did not consider that the circumstances warranted an additional ruling in relation the need to maintain high standards. No breach of the Code was ruled.

Upon appeal from Grünenthal the Appeal Board noted from Grünenthal that the licensed indication 'for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics' meant that when a health professional considered that an opioid analgesic was appropriate, that health professional could consider prescribing Palexia SR to opioid naïve patients. 65% of patients in the Palexia SR registration trials had had no prior opioid experience and less than 5% had previously taken a strong opioid.

The Appeal Board noted that the indication for Palexia SR appeared on the bottom left hand corner of the front page of the leavepiece. The company submitted that the indication was stated there so as to be near the black triangle which had to be adjacent to the most prominent display of the product name which was in the bottom right corner of the front page.

The Appeal Board noted the claim at issue and heading to page 2 stated 'Palexia SR – Unlock the potential in patients not currently taking strong opioids'. The Appeal Board noted from the company that 'strong' was included because initiation of Palexia SR was the same for patients who had not taken opioid analgesics and those that were already taking a weak opioid analgesic. Therefore page 2 dealt with these two groups of patients. Whereas page 3 headed 'Palexia SR – Unlock the potential in patients currently taking strong opioids' dealt with switching patients who were currently taking a strong opioid analgesic to Palexia SR.

The Appeal Board noted that much of the wording in the leavepiece was derived from the SPC. The Appeal Board considered that including the indication on the front page of the leavepiece sufficiently described those patients for whom

Palexia SR was indicated. The Appeal Board considered that the claim at issue on page 2 of the leavepiece was not inconsistent with the particulars listed in the SPC nor was it misleading in this regard. The Appeal Board ruled no breaches of the Code. The appeal was thus successful.

A general practitioner complained about a four page dosing and titration leavepiece (ref P11 0066) for Palexia SR (tapentadol prolonged release) issued by Grünenthal Ltd.

Page 2 of the leavepiece was headed 'Palexia SR – Unlock the potential in patients not currently taking strong opioids'. Under a sub-heading of 'Start low, go slow', advice on dosage in patients who were currently not taking strong opioids was given. Page 3 of the leavepiece was headed 'Palexia SR – Unlock the potential in patients currently taking strong opioids' and featured information on how to switch patients already on opioids to Palexia SR.

COMPLAINT

The complainant noted that Palexia SR was indicated for the management of adults with severe chronic pain which could be adequately managed only with opioid analgesics.

The complainant submitted that the leavepiece was misleading particularly on the second page where, in his view, it attempted to ask prescribers to prescribe Palexia SR for patients not currently taking strong opioids. This appeared to be outside of the licensed guidance and therefore in breach of the Code in promoting such an indication. The complainant queried why someone would want to take Palexia SR if their pain was adequately controlled by a strong opiate because there appeared to be no discernable advantages.

The third page attempted to suggest a way to switch patients on strong opiates onto Palexia SR which was within the licensed indications.

In summary, the complainant submitted that the leavepiece was possibly in breach of Clauses 7 or 9 of the Code.

When writing to Grünenthal, the Authority asked it to respond in relation to Clauses 3.2, 7.2 and 9.1 of the Code.

RESPONSE

Grünenthal submitted that the marketing authorization for Palexia SR was, as stated in the summary of product characteristics (SPC), 'Palexia SR is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics'. As such, adult patients who were not on a strong opioid could be prescribed Palexia SR if they had severe chronic pain which could be adequately managed only with opioid analgesics.

Given that the promotion of Palexia SR was in line with the terms of its marketing authorization and consistent with the particulars listed in its SPC, Grünenthal submitted that it was strictly adhering to Clause 3.2. Furthermore, the data presented was an accurate and unambiguous reflection of the marketing authorization and SPC, thus the company denied a breach of Clause 7.2. By complying with Clauses 3.2 and 7.2, Grünenthal believed that it had maintained high standards at all times as defined in Clause 9.1.

PANEL RULING

The Panel noted that the leavepiece entitled 'Starting to unlock the potential of Palexia SR (tapentadol prolonged release tablets): Dosing and titration guidance' featured on the bottom left hand corner of the front page a statement about its licensed indication: 'Palexia SR is indicated for the treatment of chronic pain in adults, which can be adequately managed only with opioid analgesics'. Page 2 began with the claim at issue and the prominent heading 'Palexia SR-Unlock the potential in patients not currently taking strong opioids'. Dosage recommendations in patients currently not taking opioid analgesics appeared beneath the subheading 'Start low, go slow'.

According to its SPC, Palexia SR was indicated for the management of severe chronic pain in adults, which could be adequately managed only with opioid analgesics.

The Panel considered that the claim at issue on page 2 implied that Palexia SR was indicated for use in all patients not currently taking strong opioids and that was not so. Its use was restricted to those patients who could be adequately managed only with opioid analgesics. Neither the claim, nor its immediate visual field nor the text below described the patient population for whom Palexia was indicated. The claim was inconsistent with the particulars listed in the SPC and misleading in this regard. The Panel noted that a statement about the licensed indication appeared at the bottom of the front page of the leavepiece but considered that this did not counter the misleading nature of the claim at issue and thus a breach of Clauses 3.2 and 7.2 was ruled. The Panel considered that this ruling adequately covered the allegation and did not consider that the circumstances warranted an additional ruling in relation to Clause 9.1 and the need to maintain high standards. No breach of Clause 9.1 was ruled.

APPEAL BY GRÜNENTHAL

Grünenthal submitted that Sections 4.1 and 4.2 of the Palexia SR SPC set out the licensed indication and the dosing information for clinical use respectively (see below). The text from these sections of the SPC was replicated and used in the leavepiece at issue in the interests of patient safety. The licensed indication did not state that a strong opioid was required to adequately manage severe

chronic pain. Furthermore, in the registration trials used to obtain the marketing authorization for Palexia SR 65.5% of patients had no prior opioid experience (Lange *et al* 2010) and less than 5% of patients had experience on strong opioids (data on file).

> '4.1 Therapeutic indications
> Palexia SR is indicated for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics.
>
> 4.2 Posology and method of administration
> The dosing regimen should be individualised according to the severity of pain being treated, the previous treatment experience and the ability to monitor the patient.
>
> Palexia SR should be taken twice daily, approximately every 12 hours.
>
> Initiation of therapy
>
> **Initiation of therapy in patients currently not taking opioid analgesics** [emphasis added]
>
> Patients should start treatment with single doses of 50mg tapentadol as prolonged-release tablet administered twice daily.
>
> **Initiation of therapy in patients currently taking opioid analgesics** [emphasis added]
>
> When switching from opioids to Palexia SR and choosing the initial dose, the nature of the previous medicinal product, administration and the mean daily dose should be taken into account. This may require higher initial doses of Palexia SR for patients currently taking opioids compared to those not having taken opioids before initiating therapy with Palexia SR.
>
> Titration and maintenance
>
> After initiation of therapy the dose should be titrated individually to a level that provides adequate analgesia and minimises undesirable effects under the close supervision of the prescribing physician.
>
> Experience from clinical trials has shown that a titration regimen in increments of 50mg tapentadol as prolonged-release tablet twice daily every 3 days was appropriate to achieve adequate pain control in most of the patients.
>
> Total daily doses of Palexia SR greater than 500mg tapentadol have not yet been studied and are therefore not recommended.'

Grünenthal submitted that the leavepiece was developed to ensure that once the physician had made an appropriate clinical decision to treat patients with Palexia SR, administration guidance of the treatment was available according to the marketing authorization and information detailed in the SPC. Providing dosing and titration guidance to the prescriber supported the use of Palexia SR to help ensure adequate clinical efficacy and patient safety. To ensure that the dosing and titration guidance was clinically meaningful, dose ratio information was required. This was not included in the SPC and the provision of this information was a key aim of the leavepiece.

The front cover of the leavepiece clearly stated:

- product name
- purpose
- that Palexia SR was indicated for the treatment of severe chronic pain in adults, which could be adequately managed only with opioid analgesics
- that tapentadol was a Controlled Drug, Schedule 2
- that health professionals could find the prescribing information on the back page.

The health professional would see the front cover first which defined the context of the leavepiece in terms of a licensed treatment population. If the leavepiece was read from the back cover first, then the prescribing information was prominently displayed, reiterating the licensed indication. In conclusion, the health professional would see on either the front or back pages the licensed indication for Palexia SR.

Grünenthal submitted that once the health professional turned to the inside of the leavepiece there was a single double page spread. This provided information from the SPC, indeed the text was replicated from the posology and method of administration section of the SPC (Section 4.2), and how to initiate Palexia SR once a suitable patient had been identified. This patient could either be currently taking an opioid analgesic (page three) or not (page two). Therefore the context of the title of page two 'Palexia SR – Unlock the potential in patients not currently taking strong opioids' had already been made clear through the licensed indication stated on page one. Grünenthal noted that all advice and each statement on page two was referenced to the SPC.

Grünenthal submitted therefore that it was clear to the health professional that Palexia SR was to be prescribed for adults who required treatment for severe, chronic pain, which could be adequately managed only with opioid analgesics. Therefore the leavepiece did not breach Clause 3.2. Moreover, the leavepiece logically laid out the nature of the product prior to providing dosing advice; therefore it did not breach Clause 7.2.

In summary, Grünenthal submitted that the claim was consistent with the SPC and therefore not misleading. The material was sufficiently complete to enable the health professional to form his/her own opinion. Grünenthal thus denied breaches of Clauses 3.2 and 7.2.

Grünenthal noted that the leavepiece had been withdrawn and it provided its revised version where the claim at the top of the front page had been changed. Grünenthal also provided a copy of its appeal slides.

COMMENTS FROM THE COMPLAINANT

The complainant maintained that page 2 of the leavepiece in question was misleading. In the complainant's view it would have made more sense to have had information on how to treat patients already taking a strong opioid on page 2 and not page 3 but due to the limited likely market share this medicine would achieve the complainant suspected the bigger market long term was in the creep into opiate naïve patients. Page 2 of the leavepiece made a stab at a market outside the existing licence.

APPEAL BOARD RULING

The Appeal Board noted Grünenthal's submission that the licensed indication 'for the management of severe chronic pain in adults, which can be adequately managed only with opioid analgesics' meant that when a health professional considered that an opioid analgesic was appropriate, that health professional could consider prescribing Palexia SR to opioid naïve patients. In that regard, in the registration trials used to obtain the marketing authorization for Palexia SR, 65.5% of patients had no prior opioid experience (Lange *et al*) and less than 5% of patients had previously taken a strong opioid (data on file).

The Appeal Board noted that Palexia SR had mu-agonistic opioid and additional noradrenaline reuptake inhibition properties. The SPC stated that all patients treated with active substances that had mu-opioid receptor agonist activity should be carefully monitored for signs of abuse and addiction. It also stated that the pharmacotherapeutic group for Palexia was 'Analgesics; opioids; other opioids'.

The Appeal Board noted that the indication for Palexia SR appeared on the bottom left hand corner of the front page of the leavepiece. The company submitted that the indication was stated there so as to be near the black triangle which had to be adjacent to the most prominent display of the product name which was in the bottom right corner of the front page.

The Appeal Board noted the claim at issue and heading to page 2 stated 'Palexia SR – Unlock the potential in patients not currently taking strong opioids'. The Appeal Board noted from the company that 'strong' was included because initiation of Palexia SR was the same for patients who had not taken opioid analgesics and those that were already taking a weak opioid analgesic. Therefore page 2 dealt with these two groups of patients. Whereas page 3 headed 'Palexia SR – Unlock the potential in patients currently taking strong opioids' dealt with switching patients who were currently taking a strong opioid analgesic to Palexia SR.

The Appeal Board noted that much of the wording in the leavepiece was derived from the SPC. The Appeal Board considered that including the indication on the front page of the leavepiece sufficiently described those patients for whom Palexia SR was indicated. The Appeal Board considered that the claim at issue on page 2 of the leavepiece was not inconsistent with the particulars listed in the SPC nor was it misleading in this regard. The Appeal Board ruled no breaches of Clauses 3.2 and 7.2. The appeal was thus successful.

During its consideration of this case the Appeal Board expressed concern that although the front page of the leavepiece stated that 'Tapentadol is a Controlled Drug, Schedule 2' it was not sufficiently clear in the leavepiece that Palexia SR was an opioid analgesic and the clinical implications this might have. The Appeal Board requested that Grünenthal be so advised.

Complaint received **30 September 2011**

Case completed **7 December 2011**

GENERAL PRACTITIONER v BOEHRINGER INGELHEIM and LILLY

Promotion of Trajenta

A general practitioner alleged that the claim that Trajenta offered 'class-comparable efficacy' was misleading and could not be substantiated given that there were no direct head-to-head studies comparing Trajenta with the other medicines in its class (dipeptidyl peptidase-4 (DPP-4) inhibitors). The claim appeared in a press release issued by Boehringer Ingelheim and Lilly.

The detailed responses from Boehringer Ingelheim and Lilly are given below.

The Panel considered, contrary to the complainant's view, that direct head-to-head studies were not necessarily needed to substantiate a claim for 'class-comparable efficacy'. 'Comparable' meant that the two products were worthy of comparison or able to be compared. The Panel did not consider that comparability implied equivalence.

The Panel noted the efficacy tables provided by both companies compared data across the products' respective summaries of product characteristics (SPCs) and detailed the HbA_{1C} lowering effect of Trajenta and the other DPP-4 inhibitors in various clinical settings. For those medicines licensed for use as a monotherapy in patients who could not take metformin the placebo corrected mean change in HbA_{1C} was -0.57% for Trajenta and -0.6%, -0.8% for sitagliptin. When the DPP-4 inhibitors were added to metformin therapy, however, greater differences in efficacy seemed to appear according to SPC data (placebo-corrected mean change in HbA_{1C} was -0.62% Trajenta; -0.7% sitagliptin; -0.8% saxagliptin and -1.1% vildagliptin). Similarly when added to existing therapy with metformin and a sulphonylurea the placebo-corrected mean change in HbA_{1C} was -0.62% with Trajenta and -0.9% with sitagliptin.

The Panel considered that the claim at issue implied that Trajenta offered class-comparable efficacy in all settings, ie whether it was used as monotherapy or in combination with other oral hypoglycaemic agents. This did not appear to be so; in all cases where figures were available the HbA_{1C} lowering effect of Trajenta was less than with other DPP-4 inhibitors. The Panel noted that the claim was based on an indirect comparison of efficacy data from various sources; principally from the figures given in the respective SPCs. There was no way of knowing whether the differences were clinically or statistically different. Given the data upon which it was based, the Panel considered that the claim that Trajenta offered 'class-comparable efficacy' was misleading and could not be substantiated. A breach of the Code was ruled. The Panel considered that the statement exaggerated the properties Trajenta and a further breach of the Code was ruled.

A general practitioner complained about a press release (UK/TRJ/00004e) issued by Boehringer Ingelheim Limited and Eli Lilly and Company Limited which had, as a sub-heading, a general comparative efficacy claim for Trajenta (linagliptin) vs other medicines in the same class.

Trajenta was a dipeptidyl peptidase-4 (DPP-4) inhibitor co-marketed by Boehringer Ingelheim and Lilly for the treatment of type 2 diabetes mellitus to improve glycaemic control in adults:

- as monotherapy in patients inadequately controlled by diet and exercise alone and for whom metformin was inappropriate due to intolerance, or contraindicated due to renal impairment
- in combination with metformin when diet and exercise plus metformin alone did not provide adequate glycaemic control.
- in combination with a sulphonylurea and metformin when diet and exercise plus dual therapy with these medicinal products did not provide adequate glycaemic control.

COMPLAINT

The complainant alleged that the claim that Trajenta was the 'Only DPP-4 inhibitor for use in adults with type 2 diabetes mellitus offering class-comparable efficacy with no requirement for dose adjustment or additional renal monitoring in renal impairment' was misleading and could not be substantiated in the absence of head-to-head comparative studies.

The complainant submitted that it appeared that Trajenta was being promoted by differentiating its use in patients with renal impairment by directly comparing it to other DPP-4 inhibitors. Whilst the latter claim might not need to be based on direct head-to-head comparative studies, surely the broad and sweeping claim that it offered class-comparable efficacy did?

When writing to Boehringer Ingelheim and Lilly, the Authority asked each to respond in relation to Clauses 7.2, 7.4 and 7.10 of the Code.

RESPONSE

Both companies submitted that the press release was for UK medical media only and timed to coincide with the official UK launch of Trajenta. Boehringer Ingelheim stated that the DPP-4 inhibitor class currently contained four licensed medicines – sitagliptin [marketed as Januvia by Merck, Sharpe & Dohme], saxagliptin [marketed as Onglyza by AstraZeneca], vildagliptin [marketed as Galvus by Novartis] and Trajenta. Each was similar in terms of their efficacy in reducing haemoglobin A_{1C} (HbA_{1C}) in adults with type 2 diabetes. Within the indications for which Trajenta was licensed, the efficacy of this class of medicines was summarised in the table below:

EFFICACY STUDIES	CHARACTERISTICS	Linagliptin (Trajenta)	Sitagliptin (Januvia)		Saxagliptin (Onglyza)			Vildagliptin (Galvus)	
Monotherapy in metformin inappropriate patients	Number	147	193	229	103	69	70	90	79
	Duration (wks)	18/52	18/52	24/52	24/52	24/52	24/52	24/52	24/52
	HbA1c:								
	Baseline	8.1%	8.0%	8.0%	8.0%	8.0%	8.0%	8.6%	8.4%
	Mean change vs. baseline	-0.44%	-0.5%	-0.6%	-0.5%	-0.7%	-0.6%	-0.8%	-0.7%
	Placebo-corrected	-0.57%	-0.6%	-0.8%	-0.6%	-0.4%	-0.4%	-0.5%	-0.7%
Add-on to metformin	Comparators/design				Saxagliptin + Metformin vs.Sitagliptin + Metformin			Vildagliptin + Met vs. Gliclazide + Metformin	
	Number	513	513		801			-	
	Duration (wks)	24	24		18/52			52	
	HbA1c:							Vilda/Gliclazide	
	Baseline	8.0%	8.0%		-			8.4%/8.5%	
	Mean change vs. baseline	-0.49%	-0.49%		-			-0.81%/-0.85%	
	Placebo-corrected	-0.64%	-0.64%		-			-	
	Per protocol analysis	-	-		-0.5%(Saxa), -0.6%(Sita)			-	
	Full analysis set	-	-		-0.4%(Saxa), -0.6%(Sita)			-	
					Saxagliptin non-inferior to Sitagliptin			Vildagliptin non-inferior to Gliclazide	
Add-on to metformin + SU			SU = Glimepiride						
	Number	778	115						
	Duration (wks)	24	-						
	HbA1c:								
	Baseline	8.2%	8.3%						
	Mean change vs. baseline	-0.72%	-0.6%						
	Placebo-corrected	-0.62%	-0.9%						

Both companies submitted that in all of the above indications, the mean placebo-corrected reduction in HbA_{1C} was similar and Boehringer Ingelheim submitted that it was not clinically significantly different across all four medicines in the class and so the efficacy of the DPP-4 inhibitors as a class was worthy of comparison, ie the efficacy of Trajenta and all other DPP-4 inhibitors was comparable. Lilly submitted that the intention of the claim at issue was to reflect similarity and not to imply direct comparisons.

Both companies noted that diabetic nephropathy and renal impairment was a common complication in type 2 diabetes and might range in severity from mild renal impairment to end-stage renal disease. Approximately one third of type 2 diabetics had renal impairment and this might cause clinicians to have to reconsider prescribing decisions for oral hypoglycaemic agents, many of which had restrictions and/or contraindications for use in these patients. All of the DPP-4 inhibitors, except Trajenta, were excreted primarily via the renal route and so in patients with moderate and severe renal impairment they either required dose adjustment and additional renal monitoring prior to use (saxagliptin) or were not recommended (sitagliptin and vildagliptin). Trajenta was the only DPP-4 inhibitor to be excreted primarily unchanged in the bile and so no dose adjustment or additional treatment-related monitoring of renal function was required for its use.

On 19 October, Trajenta became the first and 'Only DPP-4 inhibitor for use in adults with type 2 diabetes mellitus offering class-comparable efficacy with no requirement for dose adjustment or additional renal monitoring in renal impairment'. Both companies therefore denied that Trajenta had been promoted in anything other than an objective and non-exaggerated manner supporting its rational use and it consequently denied a breach of Clause 7.10. Similarly both companies considered that the claim as well as the press release upon which it headlined was accurate, fair, balanced, objective and unambiguous and represented an up-to-date evaluation of all the evidence that supported the use of the DPP-4 inhibitors in adult patients with type 2 diabetes and renal impairment. The companies did not consider that the claim was misleading or distorted, nor did it exaggerate the properties of Trajenta relative to those of the other DPP-4 inhibitors, nor did the claim unduly emphasise the properties or benefits of Trajenta. Consequently a breach of Clause 7.2 was denied. Furthermore, the companies believed the claim in question could be substantiated and they referred to the relevant summaries of product characteristics (SPCs) for the four licensed DPP-4 inhibitors.

Lilly stated that the press release in question was submitted to and approved by the Medicines and Healthcare products Regulatory Authority (MHRA) as part of its pre-vetting process. The claim 'class-comparable efficacy' added to 'no requirement for dose adjustment or additional renal monitoring' appeared only in the press material and had not been used in any promotional materials. To avoid confusion such as that expressed by the complainant, Lilly submitted that it would remove that particular claim from future press releases as well.

PANEL RULING

The Panel noted that Boehringer Ingelheim and Lilly had submitted very similar responses to this complaint, so it considered the cases together.

The Panel noted the complainant's view that direct head-to-head studies were needed to substantiate a claim for 'class-comparable efficacy'. The Panel considered that this was not necessarily so. 'Comparable' meant that the two products were worthy of comparison or able to be compared. The Panel did not consider that comparability implied equivalence.

The Panel noted the efficacy tables provided by both companies compared data across the products' respective SPCs and detailed the placebo-corrected percentage lowering of HbA_{1C} of Trajenta and the other DPP-4 inhibitors in various clinical settings. With regard to the use of those medicines licensed for use as a monotherapy in patients who could not take metformin the placebo corrected

mean change in HbA_{1C} was -0.57% for Trajenta and -0.6%, -0.8% for sitagliptin. When the DPP-4 inhibitors were added to metformin therapy, however, greater differences in efficacy seemed to appear according to data extracted from the relevant SPCs (placebo-corrected mean change in HbA_{1C} was -0.62% Trajenta; -0.7% sitagliptin; -0.8% saxagliptin and -1.1% vildagliptin). Similarly when added to existing therapy with metformin and a sulphonylurea the placebo-corrected mean change in HbA_{1C} was -0.62% with Trajenta and -0.9% with sitagliptin.

The Panel considered that the claim at issue implied that Trajenta offered class-comparable efficacy in all settings, ie whether it was used as monotherapy or in combination with other oral hypoglycaemic agents. This did not appear to be so; in all cases where figures were available the HbA_{1C} lowering effect of Trajenta was less than with other DPP-4 inhibitors. The Panel noted that the claim was based on an indirect comparison of efficacy data from various sources; principally from the figures given in the respective SPCs. There was no way of knowing whether the differences were clinically or statistically different. Given the data upon which it was based, the Panel considered that the claim that Trajenta offered 'class-comparable efficacy' was misleading and could not be substantiated. A breach of Clauses 7.2 and 7.4 was ruled. The Panel considered that the statement exaggerated the properties of Trajenta and a breach of Clause 7.10 was ruled.

Complaint received **4 October 2011**

Case completed **17 November 2011**

ANONYMOUS v GENUS

Conduct of Apo-go nurse advisor

An anonymous, uncontactable 'concerned pharmacist' complained about the conduct of a local Apo-go (apomorphine hydrochloride) nurse advisor employed by Genus Pharmaceuticals to advise patients about their medicines for Parkinson's disease.

The complainant noted that within the local area there were two extremely good and capable Parkinson's Disease Nurse Specialists (PDNSs) who managed patients with Parkinson's disease. The Apo-go nurse advisor's role was to educate professionals and patients about the use of apomorphine in Parkinson's disease and to support the PDNS with people using apomorphine. It was the role of the consultant and PDNS to advise patients about the dose of all medicines used in Parkinson's disease, including apomorphine.

The complainant was concerned that the Apo-go nurse advisor in question, who was previously a local PDNS, continued to change oral Parkinson's disease medicines and increase the dose of apomorphine. The nurse advisor was not a nurse prescriber and so should not have altered any medicines. She did not tell nurses what she had done, eg how a patient responded to apomorphine. The complainant alleged that, left to her own devices, the nurse advisor posed an immense risk to patients as the clinicians involved did not know why any changes to treatment had been made.

The detailed response from Genus is given below.

The Panel noted that the introduction to the PMCPA Constitution and Procedure stated that it was for the complainant to prove their complaint on the balance of probabilities. Anonymous complaints were accepted and, like all complaints, judged on the evidence provided by the parties.

The Panel noted that the nurse support programme offered by Genus was linked to the use of Apo-go such that the Panel considered that it was, in effect, a package deal as set out in the relevant supplementary information. The Panel noted that in accordance with the terms of the programme agreement, the nurse advisor would provide, *inter alia*, education, audit, clinical support and development, mentorship and patient support. The Panel considered that on the evidence before it the arrangements constituted a *bona fide* package deal and did not constitute a gift, benefit in kind or a pecuniary advantage given or offered to a health professional as an inducement to prescribe, supply, administer, recommend, buy or sell Apo-go contrary to the Code and no breach was thus ruled.

Given that the service offered by Genus bore the name of Apo-go and was inextricably linked with the product, it could not be considered a medical or educational good or service. The Panel noted its finding above that the arrangements constituted a *bona fide* package deal. It was not covered by the requirements in relation to a medical and educational good or service and thus no breach of the Code was ruled.

The Panel noted that the Nurse Support Programme Agreement provided that the lead consultant retained clinical responsibility for the patient and the PDNS remained the nursing lead in patient management. The Panel noted that this was reflected in the evidence submitted by Genus; anonymized patient notes indicated that the nurse advisor in question consulted the local consultant neurologist before she altered this particular patient's medication, and any change made was documented. The Panel also noted that the consultant neurologist's testimonial, submitted by Genus, stated that the Apo-go nurse advisor had 'without exception consulted me whenever a patient of mine has required any alteration of prescription (Apomorphine or any other aspect of treatment)'.

The complainant had submitted no evidence to support his/her serious complaint about the conduct of a fellow health professional. Evidence submitted by Genus showed that the nurse advisor was well respected by her colleagues. Thus, on the basis of the evidence before it the Panel considered that the nurse advisor had not failed to maintain high standards, and no breach of the Code was ruled. The Panel thus ruled no breach of Clause 2.

An anonymous, uncontactable complainant who described him/herself as a 'concerned pharmacist' complained about the conduct of a local Apo-go (apomorphine hydrochloride) nurse advisor employed by Genus Pharmaceuticals Ltd to advise patients about their medicines for Parkinson's disease.

Apo-go was indicated for the treatment of disabling motor fluctuations ('on-off' phenomena) in patients with Parkinson's disease which persisted despite individually titrated treatment with levodopa (with a peripheral decarboxylase inhibitor) and/or other dopamine agonists.

COMPLAINT

The complainant noted that within the local area there were two extremely good and capable Parkinson's disease nurse specialists (PDNSs) who managed patients with Parkinson's disease. One had worked closely with the medicines management team devising prescribing guidelines for local GPs.

The Apo-go nurse advisor's role was to educate professionals and patients about the use of apomorphine, a subcutaneous dopamine agonist treatment used in Parkinson's disease, and to support the PDNS with people using apomorphine. It was the role of the consultant and PDNS to advise patients about the dose of all medicines used in Parkinson's disease, including apomorphine. Parkinson's disease was complex and needed to be monitored by appropriate people.

The complainant was concerned that the Apo-go nurse advisor in question, who was previously a PDNS at a local health centre, continued to change oral Parkinson's disease medicines and increase the dose of apomorphine. The nurse should have contacted the local Parkinson's disease nurse to report any changes in any patients' condition to enable the consultant or nurse to change their oral medicines as necessary. The nurse advisor was not a nurse prescriber and therefore should not have altered any medicines. She did not write to the nurses to inform them of her actions, eg how a patient responded to apomorphine. She seemed to be a law unto herself and think that as she was previously a PDNS she could continue to work as such. This was not the case as she was, and had been for some time, an Apo-go nurse advisor. The complainant alleged that left to her own devices the nurse advisor posed an immense risk to patients as the clinicians involved did not have the information as to why any changes to treatment had been made.

When writing to Genus, the Authority asked it to consider the requirements of Clauses 2, 9.1, 18.1 and 18.4 of the Code.

RESPONSE

Genus submitted that the Genus Nurse Advisor in Apo-go therapy patient support programme was a successful and respected programme that had worked with NHS partners since September 2008. The programme supported the NHS in its management of people living with Parkinson's and Apo-go therapy. The programme was developed in response to an expressed health professional need, the Department of Health (DoH) Joint Working publication and a gap in healthcare provision as identified by people living with Parkinson's disease and the Parkinson's Disease Society (now Parkinson's UK).

The programme was very strongly focussed on patient benefit and safety and was aligned to best available evidence supporting the value of patient support programmes. It operated independently of the Genus commercial team and adhered to the following codes of practice and principles:

- The Nursing and Midwifery Council (NMC)
- NMC 2005, Guidelines for Records and Record Keeping
- Data Protection Act 1998
- Caldicott Guidelines
- Trust principles, terms and conditions within an honorary contract
- Parkinson's Disease Nurse Association
- Transparent and ethical practice

In terms of 'fitness to practice' each nurse in the patient support programme had Criminal Records Bureau (CRB) clearance, NMC registration, Royal College of Nursing (RCN) membership, occupational health clearance, were identity verified, and had the right to work in the UK. Additionally they had driving licence verification and professional references. Each nurse undertook regular statutory learning, was supported by the company in professional development and if not already achieved, encouraged to undertake the diploma in Parkinson's management.

Apo-go therapy was the only injectable treatment for the management of Parkinson's and so presented a particular challenge for patients and health professionals. The majority of clinical units would have only a few patients using this therapy and frequently struggled to assimilate and retain the skills needed to initiate a successful patient therapy experience. In such circumstances problems of extended hospital stays, sub-therapeutic therapies and poor patient satisfaction were not uncommon. Furthermore, a limitation on community visits from local PDNSs meant the patient and his/her family valued the input of a nurse with specific skills in the community, in this instance, the Genus Nurse Advisor in Apo-go.

The nurse team offered a range of services around Apo-go therapy but also had a significant level of knowledge in Parkinson's disease. It was not the aim of the project to act as PDNSs, nevertheless to enable holistic management each nurse had to have good general Parkinson's disease and general health knowledge. However, any patient interaction was only under the auspices of a programme agreement, trust honorary contract and established health professional relationship. Patients who benefited from the input of a nurse advisor would either already be receiving Apo-go therapy or have been identified by the prescriber as potentially benefitting from such therapy. The nurse advisors never audited or recruited patients for therapy. As stated by the complainant, a large part of the nurse's role was education about Apo-go therapy and Parkinson's disease management. Before any interaction took place between the nurse advisor and the patient, an honorary contract had to be established between the specific nurse involved and the individual trust within which she would operate.

The terms of the programme agreement setting out the parameters and limitations of the project would have been discussed and approved by the relevant health professional and trust's human resources department. On completion of, and in addition to trust contracts, the patient must have given written consent to the input of the Genus nurse advisor in Apo-go; the patient could withdraw from the care package at any time and his/her prescriber would be informed.

Genus provided testimonials to support the value of the nurse advisor in managing people living with Parkinson's disease and their Apo-go therapy. This supported the company's belief that the nurse team and the nurse in question were highly experienced, professional and effective in supporting patients receiving Apo-go therapy. Their sole aim was to improve the quality of care received by patients on Apo-go and to assist the NHS and health professionals to deliver, in a timely fashion, the best possible quality of care for patients. The Genus patient support programme worked with NHS partners to meet NHS and government initiatives to *inter alia*:

- Develop staff skill and performance
- Enhance the patient experience, provide choice and put the patient at the centre of care decisions
- Provide care at home; support family members, share skills and avoid unnecessary hospital admissions
- Effective, successful and cost saving Apo-go therapy initiation
- Promote positive aspects of Joint Working Partnership
- Support therapy guidelines (eg from the National Institute for Health and Clinical Excellence (NICE)) and improved patient care pathways.

Genus submitted that although the nurse in question had extensive experience as a PDNS, she was a nurse advisor within the Genus patient support programme and as such adhered to the scope of the programme agreement, which maintained that the prescriber was responsible for all changes/amendments to medicine and the nurse advisor supported those changes at the patient's home. This included ensuring the patient understood the recommended changes and that they made the change, and where Apo-go was concerned, supervised technical adjustments to the flow rate setting which dictated the amount of medicine delivered each hour. This was particularly important in a vulnerable patient group known to have significant cognitive changes associated with their disorder and where carer strain contributed to a reduction in quality of family life. In each instance regular verbal and written communication was maintained with the prescriber. A patient's medicine would only be changed at the clear instigation of the prescriber. The nurse would also document her practice in both patient and nurse held notes (examples were provided). Other communication included letters, calls to the GP and PDNS, although some patients did not have access to a PDNS or more than one; the primary PDNS would take precedence over any other. All documentation was treated as per NMC guidelines. In every case a patient's medicine would only be changed at the clear instigation of the prescriber who was informed throughout. Genus referred to Case AUTH/2358/9/10 in which it outlined the process by which the nurse advisors would get involved in changing a patient's medication as follows:

- The patient, responsible clinician and trust agreed to use the services of the nurse advisor as demonstrated by a signed patient consent form, programme agreement and honorary contract.

- Only when the patient had been identified and/or started on Apo-go therapy was the service of a nurse advisor initiated with a referral form (and often telephone call in addition). The nurse advisor was not involved in the recruitment of patients by any means whatsoever.

- The nurse advisor worked with the doctor and/or specialist nurse in an educational capacity to learn about and identify the nature of the parkinsonian symptoms specific to the patient in relation to Apo-go therapy. Inevitably, the patient was reviewed as a whole and this included, *inter alia*, other possible medicines, social activities, diet and sleep, etc.

- If a change in medicine was indicated and the doctor or PDNS was unable to make the changes personally eg when the patient was at home with no access to primary care Parkinson's disease services, the following steps would be taken:

  – The nurse advisor would visit the patient as agreed in consultation with relevant health professionals
  – Conduct a clinical assessment using accepted Parkinson's disease documentation, such as the Unified Parkinson's Disease Rating Scale Part III
  – Speak to the doctor and/or nurse and complete nursing notes about the patient's condition
  – The doctor/PDNS would instruct the nurse advisor to make the relevant changes, taking into account the patient's condition
  – This was recorded in the nursing/patient notes and shared with all NHS health professionals
  – The nurse advisor would conduct the follow up visits as agreed by the relevant health professional to ensure the changes had not caused any untoward effect and the anticipated benefit was realised. Each visit was recorded and the record sent back to the responsible health professional immediately
  – The only change that the nurse advisor would initiate without prior consultation was if an emergency arose, eg if the patient experienced severely low blood pressure, whereupon the Apo-go infusion was stopped, patient's safety stabilised, emergency

services called if necessary, and the responsible NHS health professional contacted immediately.
– At all times the patient was consulted and included in the care plan and could ask the nurse advisor to leave at any time.

Turning back to Case AUTH/2443/10/11, and given the extensive skill and experience of the nurse advisor at issue, long term health professional relationships and the willingness of the director of neurology at a local health centre to continue a professional working relationship, Genus refuted the complainant's allegation that 'left to her own devices the nurse advisor posed an enormous risk to patients …'. On every occasion and in every circumstance the nurse advisor adhered to the NMC Code of Conduct and fulfilled her duty of care to the patient. It was unthinkable that the Genus nurse advisors and this particular nurse would compromise patient safety given the amount of time, expertise and passion invested in maintaining and upholding the value and professionalism of nursing alongside the NMC Code of Conduct that underpinned excellent patient care provision. Nor would Genus expect its NHS partners to put the safety of their patients in her hands if they had any reason to believe she did not meet their high expectation for patient care. In fact, to demonstrate their commitment to the service they had expressed their support in emails, copies of which were provided. Therefore, Genus strongly refuted the accusation of poor standards and compromised patient safety and questioned the quality and level of evidence to support such a serious accusation. In support of safe professional practice copies of anonymised patient notes and written communication between the consultant and the Genus nurse advisor were provided.

Genus therefore concluded that, given the above evidence and information, Genus and the provision of Apo-go nurse advisors had not brought discredit to, and reduced confidence in, the industry (Clause 2). Conversely Genus had made a significant investment to develop a package of care that greatly enhanced the provision of service and quality of care delivered by the NHS to its Parkinson's disease patients and was, in effect an excellent example of the industry and the NHS working in partnership to deliver the highest level of service possible to its patients. This was in line with the aims and ambitions set out in the white paper 'Equity and Excellence, Liberating the NHS' and was about quality outcomes and the patient experience.

The Genus patient support programme was a valued service and the nurse in question was very experienced, well qualified and had received a high degree of training on a continuous basis both around the therapy area and Apo-go; this was expected of all the nurses who were ambassadors not only for Genus but also the nursing profession. They upheld the principle of considering the patient first and foremost because they:

- Treated them with care and dignity
- Took ownership for the care they provided and decisions made
- Were vigilant of any potential risk and acted accordingly to maintain patient safety

The nurses ensured that all documentation was in place and shared with all concerned; operated a transparent and open service while recognising the importance of the patient's right to confidentiality. Without exception the patient was at the centre of all care decisions and contributed to their disease management. The nurse advisor team was a significant part of the Genus package of care and continually strove to maintain and improve quality of care in which Genus encouraged patients to participate as aligned to the intent of the White Paper 'Equity and Excellence, Liberating the NHS 2010', which included the principle 'no decisions about me without me'.

Genus agreed that the nurse in question was not a nurse prescriber, had never acted as one and had never allowed patients and health professionals to believe she was qualified to prescribe. However, with many years' experience in the therapeutic management of Parkinson's disease her knowledge and skill was exceptional and greater than that of many prescribers. As a qualified nurse she administered medicines according to a prescription. The NMC's standards for medicines management stated that a nurse must know the therapeutic uses of a medicine, its normal dose, and any side effects and contraindications before it was given to a patient. A spokesperson for the Royal College of Nursing stated: 'Trusts have a shared responsibility with nursing staff to ensure they are competent in drug administration …', 'But it is down to the nurse to ensure competency is maintained and that they work within the scope of their practice to make sure they are safe [to administer medicine]'. The Medicines Act 1968 stated that prescription only medicines might only be administered by or in accordance with the directions of an appropriate practitioner. The Act did not require a written order although both the appropriate practitioner and the administering nurse were accountable for the standard of communication and harmful consequences to the patient of an administration error. Appropriate practitioners were defined as registered medical practitioners, registered dentists and nurses and midwives who complied with conditions specified by Order. Despite recent changes in prescribing law, nurses generally were not appropriate practitioners and must only administer medicines in accordance with directions issued by an appropriate practitioner. Unless instructed, there was no scope to alter the dose or change the form of a medicine by crushing or opening a capsule and to do so would be a breach of the 1968 Act. The Genus nurse advisor assumed this role within the realms of the professional relationship (with the doctor) and the honorary contract. Again, Genus questioned the evidence that postulated this specific nurse advisor was deemed incompetent and submitted there had been no breach of Clause 9.1.

The patient support programme was designed to assist and support patients who had been identified as suitable for treatment with Apo-go due to their oral therapy failing in terms of efficacy. This positioning was supported and recommended by the National Institute for Health and Clinical Excellence (NICE), as per the 2006 guidelines. This decision was made purely on the basis of the patient's condition and the advancing nature of the disease. As there was no benefit in kind to any health professionals directly there was no inducement to prescribe Apo-go. The benefits were focussed on the patients with regard to the nurse advisor support, 24/7 helpline, educational support and, of course, assistance with the dedicated infusion pump and all necessary peripherals. As part of the 'package of care' Genus did not believe this fell within the definition of 'goods and services' as usually interpreted within the Code.

In Case AUTH/2358/9/10 the Panel considered that the service was, in effect, offered as a package deal and that Clause 18.1 did not prevent the offer of package deals whereby the purchaser of particular medicines received with them other associated benefits provided that the transaction as a whole was fair and reasonable and the associated benefits were relevant to the medicines involved. In that case the Panel considered there was no information before it to suggest that the package of care offered by Genus was a gift, benefit in kind or a pecuniary advantage given or offered to a health professional as an inducement to prescribe, supply, administer, recommend, buy or sell Apo-go'.

Genus therefore strongly believed that there had been no breach of Clause 18.1 on this basis and the evidence presented above.

Genus considered that its patient support programme was an integral part of the care package which it offered to support patients who were suitable to receive Apo-go. As such, it did not believe the nurse advisors should be classed as a 'service or goods' as defined within Clause 18.4. With regard to the educational element of the package, again this was support offered to Parkinson's disease patients who were already receiving Apo-go and were specifically around the disease area and the role of Apo-go in their treatment.

In Case AUTH/2358/9/10 the Panel highlighted that 'Clause 18.4 related to the provision of medical and educational goods and services'. 'Given that the service offered by Genus … was inextricably linked with the product, it could not be considered to be a medical or educational good or service. It was not covered by Clause 18.4 and thus no breach of Clause 18.4 was ruled'.

With this in mind, again, Genus did not believe there had been any breach of Clause 18.4.

Genus submitted it had conducted a thorough review of the comments raised and had supplied supportive data and logical arguments where it believed there to be no breach of the Code.

PANEL RULING

The Panel noted that the complainant, who described him/herself as 'a concerned pharmacist' was anonymous and non contactable. The introduction to the PMCPA Constitution and Procedure stated that it was for the complainant to prove their complaint on the balance of probabilities. Anonymous complaints were accepted and, like all complaints, judged on the evidence provided by the parties.

The Nurse Support Programme Agreement stated that the programme was a non-promotional programme offered as a service to medicine by Genus. The Panel was unsure what was meant by the term 'non-promotional'. The service was linked to the use of Apo-go such that the Panel considered that it was, in effect, a package deal as set out in the supplementary information to Clause 18.1 Package Deals. The Panel noted that the relevant supplementary information provided that Clause 18.1 did not prevent the offer of package deals whereby the purchaser of particular medicines received with them other associated benefits provided that the transaction as a whole was fair and reasonable and the associated benefits were relevant to the medicines involved. The Panel noted that the Nurse Support Programme Agreement stated that the nurse advisor would provide *inter alia* education, audit, clinical support and development, mentorship and patient support. The Panel considered that on the evidence before it the arrangements constituted a *bona fide* package deal and did not constitute a gift, benefit in kind or a pecuniary advantage given or offered to a health professional as an inducement to prescribe, supply, administer, recommend, buy or sell Apo-go contrary to Clause 18.1. No breach of Clause 18.1 was thus ruled.

Clause 18.4 referred to the provision of medical and educational goods and services. The supplementary information to that clause stated that goods or services must not bear the name of any medicine. Given that the service offered by Genus bore the name of Apo-go and was inextricably linked with the product, it could not be considered a medical or educational good or service. The Panel noted its finding above that the arrangements constituted a *bona fide* package deal. It was not covered by Clause 18.4 and thus no breach of that clause was ruled.

The Panel noted its rulings above and the submissions made by Genus in relation to the conduct of the Apo-go nurse advisor in question. The Panel noted that the Nurse Support Programme Agreement provided that the lead consultant retained clinical responsibility for the patient and the PDNS remained the nursing lead in patient management. The Panel noted that this was

reflected in the evidence submitted by Genus. The Panel noted that the anonymized patient notes submitted by Genus indicated that the Apo-go nurse advisor in question consulted the local consultant neurologist before she altered this particular patient's medication, and any change made was documented. The Panel also noted that the consultant neurologist's testimonial, submitted by Genus, stated that the Apo-go nurse advisor had 'without exception consulted me whenever a patient of mine has required any alteration of prescription (Apomorphine or any other aspect of treatment)'.

The Panel noted that the complainant had submitted no evidence to support his/her serious complaint about the conduct of a fellow health professional. Evidence submitted by Genus showed that the nurse advisor was well respected by her colleagues. Thus, on the basis of the evidence before it the Panel considered that the nurse advisor had not failed to maintain high standards, and no breach of Clause 9.1 was ruled. The Panel thus ruled no breach of Clause 2.

Complaint received **14 October 2011**

Case completed **23 November 2011**

GENERAL PRACTITIONER v BOEHRINGER INGELHEIM

Sponsored article on linagliptin

In Case AUTH/2424/8/11 a general practitioner, complained about an article on linagliptin (marketed as Trajenta by Boehringer Ingelheim) which had appeared in Future Prescriber. As part of his appeal in that case, the complainant widened the scope of his complaint and subsequently requested that this be taken up as a new complaint (Case AUTH/2445/10/11).

The article, *inter alia*, compared linagliptin with other medicines in the same class and stated that its cost was anticipated to be similar (ie around £32/month).

The complainant alleged that as the article promoted linagliptin prelicence, the provision of an unconfirmed price to all health professionals, including those without budgetary responsibility, was inconsistent with the requirements for the provision of advanced notification. The complainant submitted that Future Prescriber was not an appropriate forum in which to provide such information and alleged that Boehringer Ingelheim had tried to use the article to circumvent the requirements of the Code and directly compare the cost of linagliptin with other medicines in the same class.

The detailed response from Boehringer Ingelheim is given below.

The Panel queried whether a company-sponsored article in a journal would ever satisfy the requirements of the Code with regard to the provision of advanced notification of new products and product changes, particularly the need to restrict the distribution of such information to those responsible for making policy decisions.

The Panel noted that Case AUTH/2424/8/11 had established that as Boehringer Ingelheim was inextricably linked to the production of the article it was responsible for its content under the Code.

The Panel noted that the anticipated cost of linagliptin quoted in the article was 'around £32 per month'. The actual cost of Trajenta, which had now received a marketing authorization, was £33.26 for a 28 day supply. The anticipated cost stated in the article was thus similar to the eventual cost.

The Panel noted that the complainant had alleged that citing an unconfirmed price of a medicine was inconsistent with the requirements for advanced notification. In that regard the Panel noted that the supplementary information to the Code stated that such information must indicate the *likely* cost and budgetary implications. It was not necessary to state the final confirmed cost although in the Panel's view the two costs should not be dissimilar. The Panel queried whether linagliptin was a medicine for which advanced notification could have been provided given its similarity in cost to other medicines in the same class.

The Panel did not consider that the article constituted the advance notification of Trajenta; Boehringer Ingelheim submitted that it had not used the article for that, or any other purpose. In that regard, and on the narrow grounds of the complaint, the Panel ruled no breach of the Code. The Panel noted that in Case AUTH/2424/8/11 it had considered, *inter alia*, that the article promoted Trajenta prior to the grant of a marketing authorization and in that wider sense it had already ruled a breach of the Code.

In Case AUTH/2424/8/11, a general practitioner complained about an article on linagliptin published in the July/August edition of Future Prescriber (Volume 12, Issue 2, 2011). Linagliptin (marketed as Trajenta by Boehringer Ingelheim) was granted a marketing authorization in August 2011, ie after the article had been published. As part of his appeal in Case AUTH/2424/8/11 the complainant widened the scope of his complaint and raised a matter which had not been previously considered by the Panel and which could thus not be the subject of an appeal. The complainant was so informed and he requested that the matter be taken up as a new complaint.

The article, *inter alia*, compared linagliptin with other medicines in the same class and stated that its cost was anticipated to be similar (ie around £32 per month).

COMPLAINT

The complainant stated that as the article at issue was deemed to promote linagliptin prelicence and Boehringer Ingelheim was responsible for its content, then the provision of an unconfirmed price to all health professionals, including those without budgetary responsibility, was inconsistent with the rules regarding the provision of advance notification information. The purpose of the latter was to allow budget holders to assess the impact of any new medicine based on both its efficacy and cost; Future Prescriber was clearly not the appropriate forum to achieve this as defined by the Code.

The complainant alleged that Boehringer Ingelheim had tried to use the article to circumvent the requirements of the process for advanced notification to invite a direct comparison of the cost of this medicine with others in the same class.

When writing to Boehringer Ingelheim, the Authority asked it to respond in relation to Clause 3.1.

RESPONSE

Boehringer Ingelheim explained that as in Case AUTH/2424/8/11, it did not commission the article at issue, determine its outline, authorize its contents or approve its use, and despite the article being published contrary to the company's direct instructions to the publisher, it actively limited its distribution once a complaint had been received.

In terms of the specific complaint, no price for linagliptin was mentioned in this article. Boehringer Ingelheim acknowledged that the authors had expressed an opinion that 'The cost of linagliptin is anticipated to be similar to the other already marketed DPP-4 inhibitors (ie around £32 per month)'. Again, this was not an opinion that Boehringer Ingelheim had influenced, nor had it authorized or approved the use of this statement or any other part of the article. Boehringer Ingelheim submitted that it had not used the article for any purpose and certainly not for the advance notification of a new product. Consequently Boehringer Ingelheim denied a breach of Clause 3.1.

PANEL RULING

The Panel noted that the supplementary information to Clause 3.1 stated that health authorities and health boards and their equivalents, trust hospitals and primary care trusts and groups needed to estimate their likely budgets two to three years in advance in order to meet Treasury requirements and there was a need for them to receive advance information about the introduction of new medicines, or changes to existing medicines, which might significantly affect their level of expenditure during future years. It was noted that at the time this information was required, the medicines concerned (or the changes to them) would not be the subject of marketing authorizations (though applications would often have been made) and it would thus be contrary to the Code for them to be promoted. Information might, however, be provided as long as, *inter alia*, it was directed to those responsible for making policy decisions on budgets rather than those expected to prescribe and the likely cost and budgetary implications must be indicated and must be such that they would make significant differences to the likely expenditure of health authorities and trust hospitals and the like.

The Panel queried whether publication of a company-sponsored article in a journal would ever satisfy the requirements of Clause 3 and the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, particularly with regard to the need to restrict the distribution of such information to only those responsible for making policy decisions.

The Panel noted Boehringer Ingelheim's submission with regard to its involvement in the production of the article. Nonetheless it had been established in Case AUTH/2424/8/11 that a business proposal between the publishers and Boehringer Ingelheim showed that the company had known from the outset that the article would support Trajenta. Although Boehringer Ingelheim did not pay for the article *per se*, it in effect commissioned it through an agreement to purchase 2,000 reprints. The Panel considered that Boehringer Ingelheim was inextricably linked to the production of the article and in that regard it was responsible for its content under the Code.

The Panel noted that the anticipated cost of linagliptin quoted in the article was 'around £32 per month'. The actual cost of Trajenta, which had now received a marketing authorization, was £33.26 for a 28 day supply. In that regard the Panel noted that the anticipated cost stated in the article was similar to the eventual cost.

The Panel noted that the complainant had alleged that citing an unconfirmed price of a medicine was inconsistent with the requirements for advanced notification. In that regard the Panel noted that the supplementary information to Clause 3.1, Advance Notification of New Products or Product Changes, stated that such information must indicate the *likely* cost and budgetary implications. It was not necessary to state the final confirmed cost although in the Panel's view the two costs should not be dissimilar. The Panel queried whether linagliptin was a medicine for which advanced notification could have been provided given its similarity in cost to other medicines in the same class.

The Panel did not consider that the article in question constituted in itself the advance notification of Trajenta; Boehringer Ingelheim submitted that it had not used the article for that, or any other, purpose. In that regard, and on the narrow grounds of the complaint, the Panel ruled no breach of Clause 3.1. The Panel noted that in Case AUTH/2424/8/11 it had considered, *inter alia*, that the article promoted Trajenta prior to the grant of a marketing authorization and in that wider sense it had already ruled a breach of Clause 3.1 .

Complaint received **14 October 2011**

Case completed **18 November 2011**

ANONYMOUS v CHUGAI

Conduct of representative

An anonymous complainant raised concerns about the conduct of a Chugai representative in relation to the Granoctye (lenograstim, G-CSF) business in a named UK region. The representative was alleged to have been overheard at a meeting boasting that the Granoctye business was 'wrapped up' because of 'pay offs' (the complainant quoted a low five figure sum) to local consultants which the complainant alleged 'had been going on for years'. The complainant stated that the representative had claimed that his/her manager knew about it and they were 'laughing all the way to the bank' in terms of bonus.

The detailed response from Chugai is given below.

The Panel noted that the complainant was anonymous and non-contactable. The Constitution and Procedure required the complainant to prove their complaint on the balance of probabilities. Anonymous complaints, like all complaints, were judged on the evidence provided by the parties.

The Panel noted that Chugai's review of its financial records over the last three years indicated that only three payments, totalling around £500 had been made in that time to consultants in the region in question. Two of those payments were for speaker services and one was an educational grant to support attendance at a meeting. The first and largest single payment (around £300) pre-dated both the representative's and the manager's employment with Chugai.

The Panel noted that the complainant claimed to have recently overheard the representative at a meeting in a named town. The representative had last been in that town eight weeks before the complaint was submitted, to speak to a secretary about the possibility of arranging a meeting. The Panel noted that Chugai's investigation indicated that the representative had not attended a stand meeting, speaker meeting or audio-visual meeting in the town since starting employment with Chugai.

The Panel considered that there was no evidence before it to suggest that any gift, benefit in kind or pecuniary advantage had been given or offered to a health professional as an inducement to prescribe, supply, administer, recommend, buy or sell Granocyte. No breach of the Code was ruled.

The Panel noted that the complainant had submitted no evidence to support his/her serious allegations about the conduct of the representative. Evidence submitted by Chugai did not indicate any improper payments. Thus the Panel considered that there was no evidence to indicate that the representative had failed to maintain a high standard of ethical conduct, and no breach of the Code was ruled including Clause 2.

An anonymous, non-contactable complainant raised concerns about the conduct of a Chugai Pharma UK Ltd representative in relation to the Granocyte (lenograstim, G-CSF) business in a named UK region.

Granocyte was marketed by Chugai for the reduction in duration of neutropenia in certain patients and for the mobilisation of peripheral blood progenitor cells.

COMPLAINT

The complainant stated that he/she had recently attended a meeting in a named town and overheard the representative boasting that all of the local Granocyte business was 'wrapped up' because of 'pay offs' (the complainant quoted a low five figure sum) to local consultants which 'had been going on for years'. The complainant submitted that the representative had stated his/her manager knew about it and they were now 'laughing all the way to the bank' in terms of bonus.

When writing to Chugai, the Authority asked it to consider the requirements of Clauses 2, 9.1, 15.2 and 18.1 of the Code.

RESPONSE

Chugai submitted that it took these allegations extremely seriously. All staff were aware of the need to maintain high standards between themselves and health professionals in line with the Code. The employee handbook (December 2009) detailed the Chugai business conduct guidelines including the requirement: 'Chugai will engage in fair and transparent transactions with medical institutions and organisations, suppliers and customers'. Chugai further recognised that, in line with the Code, its representatives must be paid a fixed basic salary and any addition proportional to sales of medicines must not constitute an undue proportion of their remuneration.

Chugai gave details of the representative in question's employment with the company and

industry experience generally; the representative had passed the ABPI Medical Representatives Examination some time ago (a copy of the certificate was provided). The representative had been further trained on the Code since joining Chugai. Chugai gave details of the representative's sales territory wherein approximately one third of the time was spent promoting Granocyte to health professionals; the remainder was spent promoting other products. Chugai submitted that the representative was well aware of, and was particularly distressed by, the serious nature and potential consequences of the anonymous allegations.

The representative's manager had been employed by Chugai for over a year and had many years' experience in the pharmaceutical industry.

Following receipt of the complaint, the representative and the manager were separately interviewed by two directors. Before the interviews took place, the representative's expense claims records and electronic diary entries were reviewed to ascertain what meetings had been attended by the representative in the named town over the past six months. In addition, the financial records for the past three years were reviewed to identify any payments made to consultants in the representative's territory.

Chugai submitted that the representative had never held or attended a stand meeting, speaker meeting or audio-visual meeting in the town in question; during the time at Chugai, the representative had visited the town only twice, in May 2011 to discuss with a transplant nurse and two doctors the possibility of arranging a meeting in the future and on 9 September 2011 where the representative spoke to a secretary about arranging a meeting and left a business card. Chugai stated that these visit dates were independently corroborated by expense claim records and detailed diary entries. The visit dates were also consistent with the dates identified before the face-to-face interviews. The only expenses claimed were for mileage and local car parking charges; there were no expenses associated with a stand meeting, speaker meeting, audio-visual meeting or similar on these dates. To date, the representative had not been successful in organising a meeting in the town.

Chugai submitted that the representative strenuously denied making comments about 'having the Granocyte business wrapped up because of pay-offs to local consultants' or that this 'had been going on for years' or that the '… manager knew about it and positively encouraged it' or that 'they were now laughing all the way to the bank in terms of bonus'. The representative clearly stated that he/she had never made improper payments to consultants and would never do so; he/she had no knowledge of any improper payments being made in the past and had never been asked by the manager to do anything improper. The representative had no idea where the complaint had come from and could make no sense of it.

Chugai stated that the manager also strenuously denied knowledge of any improper payments made to consultants recently or in the past and had never encouraged any of his/her staff to behave in this manner. The manager stated that the representative was very professional and hard working with a high level of integrity.

Chugai considered that the above interviews and investigations demonstrated that there was no evidence that high standards of ethical conduct had not been maintained and therefore refuted any breach of Clauses 9.1 and 15.2 of the Code.

Chugai explained that in the UK, G-CSF products were contracted by tender through a process commissioned by the Department of Health working in partnership with hospital pharmaceutical procurement colleagues across the NHS. The regional tendering process was led by the procurement lead, who was a pharmacist, and the local consultants had little or no influence or involvement in the process.

Chugai explained how the region at issue bought its G-CSF products and provided market share data which it considered clearly refuted the claim that the Granocyte business was 'wrapped up' across the region at issue.

Chugai stated that it had never, and would never, make improper payments to health professionals. Any payments were supported by a signed payment request form with supporting documentation and were approved by the managing director. All cheques above a value of £2,000 had to be signed by the managing director.

Chugai submitted that as the complaint was open ended ('going on for years'), three of its senior executives conducted a detailed review of the company's financial records over the past three years to identify all payments made to any consultants in the sales territory in question. The review did not reveal any evidence of improper payments. This review clearly showed there were no large payments of the sum mentioned by the complainant or more (cumulative or otherwise) as alleged. The three payments (totalling £523.60) that had been made to local consultants were all justifiable (details were provided). Furthermore, there was no evidence of recurring regular payments to local consultants. Chugai stated that its accounts were regularly audited and no evidence had ever been found of improper payments to health professionals. Chugai refuted any breach of Clause 18.1.

Chugai submitted that its representatives were paid a fixed basic salary. In addition, an objective based incentive scheme operated. Representatives could be bonused on achievement of territory sales targets and of agreed business objectives (details

were given). An additional amount might be paid for over achievement of the sales target and overall performance as in behaviours and overall contribution. The 2011 incentive scheme was notified to the sales representatives at the beginning of 2011. Bonus payments were paid annually and the next payments would be made in January 2012. Details of the representative's salary and bonus were given together with that for the manager.

Chugai submitted that in addition to the bonus scheme a single managing director's award was introduced at the end of 2010 for the top representative in the whole company for the year. Chugai noted that the manager was not eligible for this award.

Chugai considered that its salary levels and bonus scheme were consistent with industry standards and complied with Clause 15.7. Chugai did not believe that this level of potential bonus was consistent with the allegation of 'laughing all the way to the bank in terms of bonus'.

Chugai was very concerned that the anonymous and non-contactable complainant had not supplied any evidence in support of the untrue serious allegations and that this allegation could damage its good reputation.

In conclusion, Chugai submitted that it had taken the complaint extremely seriously and had performed a thorough investigation. Chugai strenuously denied the serious allegations and therefore that there had been any breach of the Code. In particular, Chugai refuted any breaches of Clauses 2, 9.1, 15.2 and 18.1.

PANEL RULING

The Panel noted that the complainant was anonymous and non-contactable. The introduction to the PMCPA Constitution and Procedure stated that it was for the complainant to prove their complaint on the balance of probabilities. Anonymous complaints were accepted and, like all complaints, judged on the evidence provided by the parties.

The Panel noted that Chugai's review of its financial records over the last three years indicated that only three payments, totalling £523.60, had been made in that time to consultants in the representative's sales territory. Two of these payments were for speaker services and one was an educational grant to support attendance at a meeting. The first and largest single payment (£326.80) pre-dated both the representative's and the manager's employment with Chugai.

The Panel noted that the complainant claimed to have recently overheard the representative at a meeting in a named town. The last time the representative had been in the town was eight weeks before the complaint was submitted. On that date the representative had spoken with a secretary about the possibility of arranging a meeting. The Panel noted that information taken from expense claims and diary entries, as well as from an interview indicated that the representative had not attended a stand meeting, speaker meeting or audio-visual meeting in the town since starting employment with Chugai.

The Panel considered that there was no evidence before it to suggest that any gift, benefit in kind or pecuniary advantage had been given or offered to a health professional as an inducement to prescribe, supply, administer, recommend, buy or sell Granocyte. No breach of Clause 18.1 was ruled.

The Panel noted that the complainant had submitted no evidence whatsoever to support his/her serious allegations about the conduct of the representative. Evidence submitted by Chugai did not indicate any improper payments. Thus, the Panel considered that there was no evidence to indicate that the representative had failed to maintain a high standard of ethical conduct, and no breach of Clause 15.2 was ruled. The Panel thus ruled no breach of Clauses 9.1 and 2.

Complaint received	**4 November 2011**
Case completed	**28 November 2011**

PHARMACIST v CELGENE

Alleged promotion of Vidaza

A regional cancer hospital pharmacist complained about alleged inappropriate promotional activity by Celgene in relation to Vidaza (azacitidine). Vidaza was indicated for the treatment of certain adult patients with myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML).

The complainant stated that he was invited at the time of the submission of azacitidine to the Scottish Medicines Consortium (SMC) (around about August 2011) to attend an advisory panel meeting. Payment was to include travel plus a £600 honorarium. The meeting was to take place after the submission to the SMC and the complainant was aware that other pharmacists were also approached. Just before the British Oncology Pharmacy Association (BOPA) conference, the complainant was invited to another meeting for senior regional pharmacists post-SMC, again with a £600 honorarium. The complainant was aware that two local haematologists were also approached and they had suggested that events took place with quite a number of doctors. In September/October the local haematology pharmacist was invited to participate in an advisory panel and offered a £600 honorarium. The complainant was concerned about the advisory element of the meeting. The complainant had not been to any of the meetings but an agenda he had seen did not seem to form the requirements for a genuine review panel.

The detailed response from Celgene is given below.

The Panel noted from Celgene's submission that there was only one advisory board meeting held in relation to the use of Vidaza in Scotland. The date of the meeting had been changed and thus two invitations had been sent. The meeting was held in November and attended by four clinicians, one pharmacist and three Celgene employees. The complainant did not attend the meeting. The Panel noted that the health professional invitees were selected based on their interest and work in the area of MDS.

The Panel noted that the invitation to the advisory board meeting was clear that the meeting was an advisory board and the objectives were stated. Background information for the attendees asked them to review the information provided and questions posed so as to facilitate open, in-depth discussion. The chairman was briefed to, *inter alia*, 'help drive informative and useful discussions around the provided topics'.

The Panel considered that the fee of £600 offered to attendees reflected the time spent preparing for the meeting and expected participation on the day. The Panel considered that the invitation should have referred to the preparation work required by attendees.

The Panel noted that the advisory board meeting that took place in October was not related to Vidaza. The organisation of the meeting appeared to be similar to that of the Vidaza advisory board.

The Panel did not consider that the Vidaza advisory board meeting, the arrangements or the documentation constituted disguised promotion of Vidaza. The Panel considered that the attendees were engaged as genuine consultants; there appeared to be a legitimate need for their services, the number engaged was not unreasonable to achieve the identified objectives and the payment appeared reasonable. No breach was ruled. The Panel considered that as the payment offered to attendees reflected the services provided by each it was not a pecuniary advantage offered as an inducement to prescribe. No breaches of the Code were ruled including Clause 2.

A regional cancer hospital pharmacist complained about the activities of Celgene Limited in relation to the use of Vidaza (azacitidine) in myelodysplasia.

Vidaza was licensed for the treatment of certain adult patients who were not eligible for haematopoietic stem cell transplantation with myelodysplastic syndromes (MDS), chronic myelomonocytic leukaemia (CMML) or acute myeloid leukaemia (AML).

COMPLAINT

The complainant stated that he was invited at the time of the submission of azacitidine to the Scottish Medicines Consortium (SMC) (around about August 2011) to attend an advisory panel meeting. Payment was to include travel plus a £600 honorarium. The meeting would have taken place after the submission to the SMC and the complainant was aware that other pharmacists were also approached. Just before the British Oncology Pharmacy Association (BOPA) conference, the complainant was invited to another meeting for senior regional pharmacists post-SMC, again with a £600 honorarium. The complainant stated that he was aware that two local haematologists were also approached and they had suggested that events took place with quite a number of doctors. The complainant knew that in September/October the

local haematology pharmacist was invited to participate in an advisory panel and offered a £600 honorarium. The complainant was concerned about the advisory element of the meeting. The complainant had not been to any of the meetings but remembered seeing an agenda which did not seem to form the requirements for a genuine review panel.

The complainant alleged that this was inappropriate promotional activity.

When writing to Celgene, the Authority asked it to respond in relation to Clauses 2, 9.1, 12.1, 18.1 and 20.1 of the Code.

RESPONSE

Celgene stated that Vidaza was appraised and recommended by the National Institute for Health and Clinical Excellence (NICE) in March 2011 as a treatment option for adults who were not eligible for haematopoietic stem cell transplantation and who received the treatment as per the marketing authorization (NICE TAG 218). Documentation was submitted for the SMC review in April/May 2011 and the final decision published on 12 September 2011.

Celgene proposed to hold an advisory board in Scotland to address the challenges of making Vidaza available for Scottish patients in the event of either a positive or negative decision by the SMC. It started to plan the meeting in June 2011 with the intention of inviting 6-8 clinicians and pharmacists to discuss:

- the challenge of effectively sharing information regarding this treatment option for patients with MDS (where treatment options were limited),
- how the company could support hospitals with training needs, and
- the logistical issues that potentially might be faced with the availability of Vidaza or otherwise on the NHS in Scotland

Celgene invited a doctor to chair the meeting which was initially scheduled to be held on the 13 September 2011 (at this time, being unaware of the date of publication of the SMC guidance). The meeting however, was later rescheduled because only two invitees could make that date. The invitees were selected based on their interest and work in the area of MDS while trying to ensure there was a fair representation from different health boards in Scotland.

Celgene stated that the initial list of proposed invitees was shared with the chair and, based on his feedback, the list was refined. All but one of the initial invitees were re-invited together with a further 10 clinicians and pharmacists (of whom the complainant was one). The meeting was eventually held on 14 November 2011, the week after the complainant submitted his complaint. No advisory board relating to the use of azacitidine in Scotland had been held before the complaint was received.

In the event, nine responses were received from the invitees, and the meeting was attended by four clinicians, including the chairman, and one pharmacist. Three Celgene attendees were at the meeting to respond to questions and clarify information if required. The discussion guide and the agenda for the meeting were provided. Celgene considered that it was clear that the purpose of the meeting was to solicit advice and engage in discussions with the experts following the positive decision from the SMC. Celgene submitted that no presentations were delivered by the Celgene attendees. The chairman ran the meeting and the meeting notes (taken by one of the Celgene attendees) were to be written up and shared with the advisory board participants.

The honorarium of £600 was offered on the basis of the time required for the participants to prepare for and attend the three hour meeting. Celgene considered that this was a fair market value for the time and input required. Reimbursement of genuine travel costs was standard practice. Celgene presumed that, because the meeting was rescheduled and the invitations therefore sent twice, the complainant mistakenly believed another similar meeting had been held. The timing of the SMC advice publication and initial date of the meeting was coincidental as this date was confirmed with the chair on 1 July 2011 when the date of the SMC advice publication was unknown. Celgene was surprised that it was reported that two haematologists suggested that a meeting took place with quite a number of doctors at the time; no such meeting had taken place.

Celgene stated that a separate meeting held in October 2011, from midday until 5pm in Glasgow, was a network pharmacists advisory board which did not discuss azacitidine and was attended by six senior network pharmacists from across the UK. It was held immediately prior to the BOPA annual meeting, 14-16 October, to facilitate attendance by the invited experts. The objectives of the meeting were to understand the nature and possible UK funding pathways for Celgene's developmental product, romidepsin, and indication extensions for lenalidomide. Four Celgene employees also attended the meeting. The agenda did not include any presentations by Celgene and it was driven by the chairman. An honorarium of £500 was offered. Celgene received significant useful advice and the write up of the meeting was recently shared with the attendees. As explained above, this meeting was unrelated in any way to the activities surrounding azacitidine or the SMC. The discussion guide and the agenda for the advisory board were provided.

Celgene stated that all the materials and arrangements relating to both advisory boards were reviewed and approved. The company's standard operating procedure (SOP) relating to meetings was provided.

Celgene considered that it had always maintained the high standards expected of the pharmaceutical industry. It had not disguised its promotional activities in any way and had always ensured the purpose of its advisory boards had been clearly communicated. The remuneration to the health professionals attending the advisory boards was reasonable and reflected fair market value for the services provided. Celgene therefore submitted that it had fully complied with the Code and had not breached Clauses 2, 9.1, 12.1, 18.1, or 20.1.

There were currently no further plans for Vidaza or pharmacy advisory boards to take place in the UK, and no further SMC-related advisory boards were planned.

PANEL RULING

The Panel noted from Celgene's submission that there was only one advisory board meeting held in relation to the use of Vidaza in Scotland. The date of the meeting had been changed and thus two invitations had been sent. The advisory board meeting was held in November and attended by four clinicians, one pharmacist and three Celgene employees. The complainant did not attend the meeting. The Panel noted that the health professional invitees were selected based on their interest and work in the area of MDS.

The Panel noted that the invitation for the MDS advisory board meeting was clear that the meeting was an advisory board, and stated the objectives to be 'to review and discuss with your colleagues attending:

- Vidaza (azacitidine) and managing SMC outcome
- Scottish clinical practice and treatment pattern
- Dosing and administration challenges for Scotland and Vidaza (azacitidine)
- Cytogenic testing
- Potential opportunities for collaboration of clinicians and industry in improving care of MDS and AML patients in Scotland'

Background information for the attendees reminded them of the meeting objectives and asked them to review the information provided and questions posed so as to facilitate open, in-depth discussion. The chairman was briefed to, *inter alia*, 'help drive informative and useful discussions around the provided topics'.

The Panel considered that the fee of £600 offered to attendees reflected the time spent in preparation for the meeting and expected participation on the day. The Panel considered that the invitation should have referred to the preparation work required by attendees.

The Panel noted Celgene's submission that the meeting was run by the chairman with no presentations given at the meeting by any of the Celgene employees who had attended. The employees had been present to answer questions or provide clarification when required. One of the employees had taken meeting notes.

The Panel noted that the advisory board meeting that took place in October was not related to Vidaza. The organisation of the meeting appeared to be similar to that of the Vidaza advisory board, in that the invitation set out the objectives of the meeting. Background information was provided to attendees which included questions relating to each objective to be considered during the discussion. Again the Panel considered that the invitation should have referred to the preparation work required by attendees.

The Panel did not consider that the Vidaza advisory board was promotional. The invitation was clear that the meeting was an advisory board and included the meeting objectives. The agenda indicated a number of discussions based around the stated objectives. Background reading and preparation was required. The Panel did not consider that either the meeting or the documentation constituted disguised promotion of Vidaza. No breach of Clause 12.1 was ruled. The Panel considered that the attendees were engaged as genuine consultants; there appeared to be a legitimate need for their services, the number engaged was not unreasonable to achieve the identified objectives and the compensation provided in return for their services appeared reasonable. No breach of Clause 20.1 was ruled. The Panel noted its rulings of no breach above and thus considered that as the payment offered to attendees reflected the services provided by each it was not a pecuniary advantage offered as an inducement to prescribe. The Panel ruled no breach of Clause 18.1. Given its rulings above the Panel also ruled no breach of Clauses 9.1 and 2.

Complaint received **7 November 2011**

Case completed **20 December 2011**

CASE AUTH/2455/11/11

ANONYMOUS v ALLERGAN

Botox tweet

An anonymous, non-contactable complainant alleged that a tweet sent by an Allergan employee to a patient organisation and an individual representing that organisation was in breach of the Code. The tweet referred to Botox and stated '… we could do something around stroke rehab …'. Botox was indicated, *inter alia*, for certain spasticity associated with stroke in adults.

The detailed response from Allergan is given below.

The Panel noted Allergan's submission that its employee had used a personal Twitter account to respond to a tweet from a friend who worked for an agency that worked for the patient organisation. The tweet referred to Botox and rehabilitation in stroke. The Panel noted that although the tweet was intended to be a private message to a friend, tweets were much more public and so in that regard it considered that a prescription only medicine had been advertised to the public. A breach of the Code was ruled as acknowledged by Allergan. High standards had not been maintained. A further breach of the Code was ruled.

The Panel noted that the tweet was sent in error by an individual using a personal account and without the knowledge or authority of Allergan. Pharmaceutical company employees needed to ensure that business relationships and personal relationships were kept very separate particularly when such business relationships were subject to the Code. In the Panel's view pharmaceutical company employees needed to be extremely cautious when using social media. Allergan's company policy clearly stated no Allergan employee might comment in a social media forum about an Allergan product or business activity. The Panel thus noted that Allergan had a policy in place which should have prevented the tweet being sent. The Panel considered that Allergan had been badly let down by its employee. Nonetheless the Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of that clause was ruled.

An anonymous, non-contactable complainant complained about a tweet from an Allergan employee to an individual at a patient organisation. The tweet referred to the sender's association with Botox (botulinum toxin, marketed by Allergan) and included '… we could do something around stroke rehab'. Botox had a number of indications including certain spasticity associated with stroke in adults.

COMPLAINT

The complainant noted that the tweet at issue was sent proactively by an Allergan employee to a patient organisation and an individual representing that organisation. The tweet mentioned Botox by brand name and included '… we could do something around stroke rehab …'. The complainant alleged a breach of the Code.

When writing to Allergan, the Authority asked it to respond in relation to Clauses 2, 9.1 and 22.1 of the Code.

RESPONSE

Allergan confirmed that the tweet intercepted by the complainant was sent by one of its employees. It was sent on a private and confidential basis, and was not approved or authorised by Allergan.

Allergan explained that the employee concerned was an occasional user of Twitter (details were provided). The account was entirely personal and not connected with Allergan. The tweet at issue was sent in response to a tweet from a friend whom the employee had known for approximately ten years and was following on Twitter. This friend worked for an agency which worked for a patient organisation. Allergan submitted that the original tweet and the response were the only communication on this matter. Copies of the tweets were provided.

Allergan submitted that its employee had intended to reply directly as a private message to a friend (as in an email), and so was not aware that the reply was accessible not only to the friend, but also to his/her followers and the Twitter followers of the patient organisation he/she worked for. As soon as the matter was brought to the Allergan employee's attention the tweet at issue was deleted from Twitter. The Twitter account had been closed.

The individual concerned knew that the tweet at issue should not have been sent, either to an individual (and/or their followers) or to a patient organisation. Whilst this was a genuine mistake by an infrequent user of Twitter, the employee was aware of his/her error in this matter and had been told that the sending of the tweet violated Allergan's Global Social Media Policy. This policy covered personal use of social media and clearly stated that Allergan would respond promptly to any potential violations of its policy. A copy was provided.

The employee had also been told that the sending of the tweet was in breach of Clause 22.1 of the Code. Any potential breaches of the Code by employees were promptly investigated by Allergan. A full internal investigation had been instigated and would result in appropriate disciplinary action.

Allergan submitted that it took this matter extremely seriously and, apart from actions being undertaken with the employee, it had looked at training on social media in general and had updated its social media policy. Allergan would include further emphasis on the personal use of social media.

All UK employees had been sent an update on the use of social media together with a copy of the PMCPA guidance on digital communications and training materials on the Code would be updated to include a specific section on social media.

Regarding the potential breaches of the Code, Allergan acknowledged that the sending of the tweet was a breach of Clause 22.1.

Allergan noted that this was an error by an individual, rather than a company failure. The employee's error in inappropriately replying to a tweet from a friend, compounded by inexperience with the use of Twitter, resulted in the tweet also being sent to Twitter followers of a patient organisation.

Allergan stated that it appreciated the serious nature of this issue and had undertaken appropriate remedial action. However, it did not believe this was a breach of either Clause 9.1 or Clause 2. Allergan had clear policies in place and training was provided on both internal Allergan policies and the Code.

PANEL RULING

The Panel noted Allergan's submission that the individual concerned had used his/her own personal Twitter account to respond to a tweet from a friend who worked for an agency that worked for a patient association. The tweet referred to Botox and rehabilitation in stroke. The Panel noted that the tweet was intended to be a private message to a friend as in an email but tweets were much more public. According to Allergan this tweet had been sent to the friend, the friend's followers and followers of the patient organisation. The sender was described as an occasional and inexperienced user of Twitter.

The Panel noted that the tweet named a prescription only medicine (Botox) and referred to a potential use (rehabilitation following a stroke). In that regard the Panel considered that a prescription only medicine had been advertised to the public. A breach of Clause 22.1 was ruled as acknowledged by Allergan. High standards had not been maintained. A breach of Clause 9.1 was ruled.

The Panel noted that the tweet was sent in error by an individual using their own account and without the knowledge or authority of Allergan. The sender's Twitter account had been closed. The Panel considered that pharmaceutical company employees needed to ensure that business relationships and personal relationships were kept very separate particularly when such business relationships were subject to the Code. In the Panel's view pharmaceutical company employees needed to be extremely cautious when using social media. It noted that the Allergan Global Social Media Policy clearly stated with regard to personal use of social media that users might not address Allergan-related topics unless specifically authorized by Allergan to do so. As an example it was stated that no Allergan employee might comment in a social media forum about an Allergan product or business activity. The Panel thus noted that Allergan had a policy in place which should have prevented the tweet being sent. The Panel considered that Allergan had been badly let down by its employee. Nonetheless the Panel did not consider that this case warranted a ruling of a breach of Clause 2 which was a sign of particular censure and reserved for such. No breach of Clause 2 was ruled.

Complaint received **10 November 2011**

Case completed **13 December 2011**

GENERAL PRACTITIONER v TEVA

Promotion of Qvar

A general practitioner and ex-employee of Cephalon (UK) complained about an advertisement for Qvar (CFC-free beclometasone dipropionate) issued by Teva and published in the BMJ, 10 September 2011. Qvar was indicated for the prophylactic management of mild, moderate or severe asthma.

Cephalon had been acquired by Teva on 14 October 2011.

The detailed response from Teva is given below.

The complainant was concerned that omitting information about the confidence limits in relation to a claim 'Qvar Easi-Breathe has real-life data from real-life patients. It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …' which was referenced to a poster by McKnight *et al* 2010, could be misleading if the confidence intervals suggested much smaller or no differences were also likely. Secondly, no p values were presented which could further impact prescribing decisions. Therefore, overall, the statistical information was insufficient to make a clear prescribing decision and the omission of key statistical information was potentially misleading.

The Panel noted that the Code did not require the inclusion of statistical information. It required that claims were not misleading and were capable of substantiation but the omission of statistical information was not in itself necessarily misleading. The supplementary information advised that care be taken to ensure that there was a sound statistical basis for all information, claims and comparisons. Differences which did not reach statistical significance must not be presented in such a way as to mislead.

The Panel noted that one of the three results from McKnight *et al* compared patients using breath activated inhaler (Qvar Easi-Breathe) and pMDI beclometasone (Clenil pMDI). Patients were in three categories, controlled, partly controlled and uncontrolled. McKnight *et al* stated that in this population Qvar Easi-Breathe was associated with better control than Clenil pMDI (p <0.04). The Panel noted that the claim at issue 'It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …' was different to the conclusions of McKnight *et al* which used the phrases 'appeared to result in better control' and 'is associated with better control'.

The Panel had some concerns about the claim. However, it did not consider that it was misleading due to the absence of confidence intervals or p values as alleged. No breach was ruled.

The complainant noted that whilst not obligatory, it would have been helpful to provide a telephone number and/or email address to report possible adverse events, or to request further information, without recourse to another source.

The Panel noted that the statement in the advertisement that 'Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Teva UK Limited' was in line with the Code. The supplementary information stated that a telephone number or email address could be included but there was no requirement to do so. The Panel therefore ruled no breach.

A general practitioner and ex-employee of Cephalon (UK) Ltd complained about an advertisement (Ref QV/11/003d) for Qvar (CFC-free beclometasone dipropionate) issued by Teva UK Limited and published in the BMJ, 10 September 2011 (Ref QV/11/003d). Qvar was indicated for the prophylactic management of mild, moderate or severe asthma.

Cephalon had been acquired by Teva on 14 October 2011.

1 **Claim 'Qvar Easi-Breathe has real-life data from real-life patients. It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …'**

The asterisk took the reader to the footnote 'Pressurised Metered Dose Inhaler. Percentage controlled on Qvar Easi-Breathe 64% (0.64). Percentage controlled on Clenil Modulite = 54%. Therefore ARR is 0.64 – 0.54 = 0.1. Numbers needed to treat = 10'.

The claim was referenced to a poster by McKnight *et al* presented at the European Respiratory Society congress, 2010.

COMPLAINT

The complainant was concerned that there was not enough information to make a decision on the clinical utility of Qvar, in breach of Clause 7.2.

No confidence intervals were provided to determine how large or small an effect was observed, and whether the confidence intervals for each group overlapped, which raised the possibility that there was no difference between the groups. The complainant alleged that omitting this information could be misleading if the confidence intervals suggested much smaller or no differences were also likely. Secondly, no p values were presented to interpret what level of statistical significance was used which could further impact prescribing decisions in combination with confidence intervals. Therefore, overall, the statistical information was insufficient to make a clear prescribing decision and the omission of key statistical information was potentially misleading in breach of Clause 7.2 and a comparative claim in breach of Clause 7.3.

RESPONSE

Teva submitted that the allegation about insufficient information was a misrepresentation due to oversimplification of Clause 7.2 which stated:

> 'Information, claims and comparisons must be accurate, balanced, fair, objective and unambiguous and must be based on an up-to-date evaluation of all the evidence and reflect that evidence clearly. They must not mislead either directly or by implication, by distortion, exaggeration or undue emphasis.
>
> Material must be sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicine.'

Teva considered that the advertisement complied with Clause 7.2 as it was accurate, balanced, fair, objective and unambiguous and based on an up-to-date evaluation of McKnight *et al* (2010) and clearly reflected that poster presentation. It did not mislead and was sufficiently complete to enable a health professional to form his/her own opinion of the therapeutic value of the medicine as detailed in McKnight *et al*. All claims were clearly referenced and were capable of substantiation.

Confidence intervals were not included as they were not presented in the poster for the measure quoted in the advertisement, as the analysis did not calculate confidence intervals.

With regard to the p value, Teva submitted that the Code did not require statistical numerical data such as the p value to be provided. The Code clearly stated in Clause 7.4 that 'Any information, claim or comparison must be capable of substantiation'. The p value and statement of significance was substantiated by the poster cited in support of the claim.

Teva submitted that the claim at issue was clear, concise and referenced appropriately and reflected McKnight *et al*.

Teva denied that the advertisement was misleading. The advertisement used an appropriate comparator product, detailed claims that were substantiable in the original reference, created no confusion, reflected trademarks, took no unfair advantage in the reputation of the trademark and was not presented as an imitation or replica. It reflected the original reference and therefore did not breach Clause 7.3.

Teva submitted that the Code did not require the level of detail highlighted by the complainant and the advertisement was factually correct, unambiguous and referenced accordingly. The Code required that claims must not be misleading and be capable of substantiation, which was so for the advertisement at issue.

PANEL RULING

The Panel noted that the Code did not require the inclusion of statistical information. It required that claims were not misleading and were capable of substantiation but the omission of statistical information was not in itself necessarily misleading. The supplementary information to Clause 7, statistical information, advised that care be taken to ensure that there was a sound statistical basis for all information, claims and comparisons. Differences which did not reach statistical significance must not be presented in such a way as to mislead.

The Panel noted that McKnight *et al* predominantly focussed on retrospectively evaluating asthma control and how it was influenced by inhaler technique. One of the three results compared patients using breath activated inhaler (Qvar Easi-Breathe) and pMDI beclometasone (Clenil pMDI) using a modified form of the Global Initiative for Asthma (GINA) control tool. Patients on Clenil were compared with patients on Qvar in three categories, controlled, partly controlled and uncontrolled. McKnight *et al* stated that in this population Qvar Easi-Breathe was associated with better control than Clenil pMDI ($p < 0.04$). The Panel noted that the claim at issue 'It shows significantly more patients using Qvar Easi-Breathe had their asthma controlled than patients using Clenil Modulite pMDI* …' was different to the conclusions of McKnight *et al* which used the phrases 'appeared to result in better control' and 'is associated with better control'.

The Panel had some concerns about the claim. However, it did not consider that the claim at issue was misleading due to the absence of confidence intervals or p values as alleged. No breach of Clauses 7.2 and 7.3 was ruled.

2 Provision of contact details

COMPLAINT

The complainant noted that whilst not obligatory, it would have been helpful if Teva had provided a

telephone number and/or email address to report possible adverse events (Clause 4.10 supplementary information), or to request further information, without recourse to another source.

RESPONSE

Teva stated that a company telephone number and/or email address to report adverse events was not obligatory, therefore it did not understand why the complaint had been made. Teva submitted that it had provided the necessary obligatory information and it reserved the right to include/exclude supplementary information. This would be reviewed when the company revised its procedures with the introduction of the 2012 Code.

PANEL RULING

The Panel noted that the statement in the advertisement that 'Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Teva UK Limited' was in line with the requirements of Clause 4.10. The supplementary information stated that a telephone number or email address could be included but there was no requirement to do so. The Panel therefore ruled no breach of Clause 4.10.

Complaint received **17 November 2011**

Case completed **9 January 2012**

CASE AUTH/2458/11/11

VOLUNTARY ADMISSION BY ABBOTT LABORATORIES

Medical Representatives Examination

Abbott Laboratories advised the Authority that one of its representatives had not taken the ABPI Medical Representatives Examination, in breach of the Code.

In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

Abbott stated that a review of representatives' certificates for passing the ABPI representatives examination showed a representative who entered the industry ten years before starting work with Abbott in the early 1990s, had not taken the examination. All other representatives were compliant with the Code requirement.

When the Code changed in 2006 the representative's manager stated in an email that the representative had sat the examination. This was incorrect.

The detailed response from Abbott is given below.

The Panel noted that the representative had a nursing qualification and had entered the industry at a time when this qualification exempted the representative from having to take the examination. That exemption, however, was removed in 2006 and all representatives who had previously been exempt had then to be entered for the examination by January 2007 and pass it by January 2008.

The Panel noted that the representative had received training on the Code and related company policies and procedures. The representative had not, however, passed the examination contrary to the requirements of the Code. A breach of the Code was ruled as acknowledged by Abbott.

Abbott Laboratories Limited advised the Authority that one of its representatives had not taken the ABPI Medical Representatives Examination, in breach of Clause 16.3 of the Code.

In accordance with Paragraph 5.6 of the Constitution and Procedure for the Prescription Medicines Code of Practice Authority, the Director treated the matter as a complaint.

COMPLAINT

Abbott stated that following a recent review of representatives' certificates for passing the ABPI representatives examination it became apparent that one of its representatives who entered the industry ten years before starting work with Abbott in 1992, had not taken the examination. As soon as this information was discovered the representative stopped working in the field until some resolution could be found.

When the Code changed in 2006 the representative's manager stated in an email that the representative had sat the examination. This now appeared to be incorrect and the manager no longer worked for Abbott.

All other representatives were compliant with the Code requirement.

When writing to Abbott, the Authority asked it to provide any further comments in relation to Clause 16.3 of the Code.

RESPONSE

Abbott stated that on investigation it became apparent that the representative believed a nursing qualification meant he/she was exempt. Abbott could not find formal documentation in relation to the representative's examination status when the representative joined the company. In 2006, with the Code change, Abbott carried out a review. At this point the representative was on leave and it was the duty of the manager to have followed up on the representative's qualifications. However, it appeared that this was not completed. The manager no longer worked for Abbott and thus the company was unable to investigate further.

In summary, Abbott had failed to appropriately check and document the representative's examination status. A full review had confirmed there were no other representatives who were either unqualified or not currently working towards the examination. More recent contracts of employment for representatives had included a clause that all representatives must pass the ABPI examination within the allotted time frame; however, this was not the case when the representative at issue was employed. Following this incident, discovered during an internal compliance check, a more formal checking and documentation process was being implemented.

PANEL RULING

The Panel noted that Clause 16.3 stated that representatives must pass the appropriate ABPI representatives' examination. They must take the appropriate examination within their first year of

such employment. Prior to passing the appropriate examination, they might be engaged in such employment for not more than two years, whether continuous or otherwise. The relevant supplementary information gave the Director discretion to grant an extension in the event of failure to comply with either time limit subject to the representative taking or passing the examination within a reasonable time.

The Panel noted that the representative, who had a nursing qualification, had entered the industry at a time when this qualification would have exempted the representative from having to take the examination. That exemption, however, was removed in 2006 and all representatives who had previously been exempt from the examination had then to be entered for it by January 2007 and pass it by January 2008.

The Panel noted that on 20 January 2006 an email was sent from the training department at Abbott to all regional managers, notifying them of the changes to the ABPI examination. Under a bold blue sub-heading of 'New: There are no longer any exemptions for taking and passing the ABPI Exam' it was clearly stated that previously exempt persons must now take the examination before January 2007 and pass it before January 2008. The email stated, *inter alia*: 'In order to ascertain the number of representatives (or indeed Regional Managers) this new ruling will affect, can you please let me know the names of anyone in your region who has previously been exempt and therefore not passed the exam'.

The Panel noted that the response to this email from the then manager of the representative in question stated that all the manager's representatives were 'up to speed re changes to ABPI Exam new code 2006'. The Panel considered that this response did not clearly answer the question asked and was ambiguous in relation to whether all this manager's representatives had indeed passed the ABPI examination, and clarification should have been sought. The email did not state that the representative had sat the examination as submitted by Abbott.

The Panel noted that the representative's training record showed that she had received training on the Code and related company policies and procedures. The representative had not, however, passed the examination contrary to the requirements of Clause 16.3. A breach of that clause was ruled as acknowledged by Abbott.

Complaint received **17 November 2011**

Case completed **4 January 2012**

CODE OF PRACTICE REVIEW – February 2012

Cases in which a breach of the Code was ruled are indexed in **bold type.**

2410/6/11	Hospital Physician v Bristol-Myers Squibb	Representatives training event	No breach	Appeal by respondent	Page 3
2414/6/11	Hospital doctor v AstraZeneca	Representative training event	No breach	Appeal by respondent	Page 14
2424/8/11 and 2425/8/11	**General practitioner v Boehringer Ingelheim and Lilly**	**Sponsored article on linagliptin**	**Boehringer Ingelheim – breaches Clauses 2, 3.1, 7.2, 7.4, 7.9, 7.10, 9.1 and 12.1** **Lilly – No breach**	**Appeal by complainant in 2424/8/11**	**Page 41**
2426/8/11 and 2427/8/11, 2428/8/11 and 2429/8/12	Members of the public v AstraZeneca and Bristol-Myers Squibb	Onglyza advertisement in the Health Service Journal	No breach	Appeal by respondents in all cases	Page 49
2436/9/11	**Genzyme v Shire**	**VPRIV website**	**Three breaches Clause 7.2 Breach Clause 7.3**	**No appeal**	**Page 53**
2439/9/11	General practitioner v Grünenthal	Promotion of Palexia	No breach	Appeal by respondent	Page 58
2440/10/11 and 2441/10/11	**General practitioner v Boehringer Ingelheim and Lilly**	**Promotion of Trajenta**	**Breaches Clauses 7.2, 7.4 and 7.10**	**No appeal**	**Page 62**
2443/10/11	Anonymous v Genus	Conduct of Apo-go nurse advisor	No breach	No appeal	Page 65
2445/10/11	General practitioner v Boehringer Ingelheim	Sponsored article on linagliptin	No breach	No appeal	Page 71
2453/11/11	Anonymous v Chugai	Conduct of representative	No breach	No appeal	Page 73
2454/11/11	Pharmacist v Celgene	Alleged promotion of Vidaza	No breach	No appeal	Page 76
2455/11/11	**Anonymous v Allergan**	**Botox tweet**	**Breaches Clauses 9.1 and 22.1**	**No appeal**	**Page 79**
2457/11/11	General practitioner v Teva	Promotion of Qvar	No breach	No appeal	Page 81
2458/11/11	**Voluntary admission by Abbott Laboratories**	**Medical representatives examination**	**Breach Clause 16.3**	**No appeal**	**Page 84**

PMCPA | Prescription Medicines Code of Practice Authority

The Prescription Medicines Code of Practice Authority was established by The Association of the British Pharmaceutical Industry (ABPI) in 1993 to operate the Code of Practice for the Pharmaceutical Industry at arm's length from the ABPI itself. Compliance with the Code is obligatory for ABPI member companies and, in addition, over sixty non member companies have voluntarily agreed to comply with the Code and to accept the jurisdiction of the Authority.

The Code covers the advertising of medicines to health professionals and administrative staff and also covers information about prescription only medicines made available to the public.

It covers:

- journal and direct mail advertising
- the activities of representatives, including detail aids and other printed material used by representatives
- the supply of samples
- the provision of inducements to prescribe, supply, administer, recommend, buy or sell medicines by the gift, offer or promise of any benefit or bonus, whether in money or in kind
- the provision of hospitality
- the organisation of promotional meetings
- the sponsorship of scientific and other meetings, including payment of travelling and accommodation expenses
- the sponsorship of attendance at meetings organised by third parties
- all other sales promotion in whatever form, such as participation in exhibitions, the use of audio or video-recordings in any format, broadcast media, non-print media, the Internet, interactive data systems and the like.

It also covers:

- the provision of information on prescription only medicines to the public either directly or indirectly, including by means of internet
- relationships with patient organisations
- the use of consultants
- non-interventional studies of marketed medicines
- the provision of items for patients
- the provision of medical and educational goods and services
- grants and donations to institutions.

Complaints submitted under the Code are considered by the Code of Practice Panel which consists of the four members of the Code of Practice Authority acting with the assistance of independent expert advisers where appropriate. One member of the Panel acts as case preparation manager for a particular case and that member is neither present nor participates when the Panel considers it.

Both complainants and respondents may appeal to the Code of Practice Appeal Board against rulings made by the Panel. The Code of Practice Appeal Board is chaired by an independent legally qualified Chairman, Mr William Harbage QC, and includes independent members from outside the industry. Independent members, including the Chairman, are always in a majority when matters are considered by the Appeal Board.

In each case where a breach of the Code is ruled, the company concerned must give an undertaking that the practice in question has ceased forthwith and that all possible steps have been taken to avoid a similar breach in the future. An undertaking must be accompanied by details of the action taken to implement the ruling. Additional sanctions are imposed in serious cases.

Complaints under the Code should be sent to the Director of the Prescription Medicines Code of Practice Authority, 7th Floor, Southside, 105 Victoria Street, London SW1E 6QT

telephone 020 7747 8880
facsimile 020 7747 8881
by email to: complaints@pmcpa.org.uk.