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**