

MYOCARDIAL INFARCTION NATIONAL AUDIT PROJECT v SANOFI-AVENTIS AND BRISTOL-MYERS SQUIBB

Sponsored meetings

The Myocardial Infarction National Audit Project (MINAP) complained about the activities of an agency working on behalf of Sanofi-Aventis and Bristol-Myers Squibb and, in particular, an invitation to a meeting.

The complainant noted that MINAP collected and analysed data on acute myocardial infarction from all acute hospitals in England and Wales. It had existed since 2000 and was now one of the world's largest audits of myocardial infarction. It was funded by the Healthcare Commission. Involvement with MINAP was mandatory for acute hospitals and MINAP analyses were used to measure hospital performance and as evidence of collaboration in national audit by the Healthcare Commission.

MINAP had a strong presence within the cardiac community and was widely recognised as a very successful long term national project which had resulted in major improvements in cardiac care. It was highly respected as a source of national data on care for acute myocardial infarction. MINAP had never solicited support from industry; it was the view of the MINAP steering group that MINAP should have no involvement with the pharmaceutical industry.

The complainant stated that in summer 2006 a member of the MINAP steering group told him about a local collaboration in which she and a colleague, together with Bristol-Myers Squibb, would develop a toolkit to assist local hospitals make the best use of MINAP data. The complainant understood that the cost was to be funded by an unrestricted educational grant from Bristol-Myers Squibb.

The complainant stated that on presenting this work to the MINAP steering group his colleague had been advised to proceed with great caution with any involvement with industry, and that MINAP itself would not become directly involved. Nevertheless, on the basis that Bristol-Myers Squibb would support the development of the toolkit the complainant met the agency which was involved in developing the toolkit on behalf of Bristol-Myers Squibb, in order to hear more of its proposals. This consisted of developing the toolkit – on the basis of ideas provided locally – and presenting this work at a series of seminars involving clinicians, nurses, audit staff, and cardiac network staff throughout the country. It was stated by the agency that funding was unrestricted. After the meeting those involved with the project had misgivings about the direction in

which it was moving, and in particular it became clear that support was not unrestricted and that they were going to be working on an enterprise which had clear commercial involvement and which would involve promotion, either directly or indirectly, of relevant pharmaceutical products.

As MINAP was a national project funded by the Healthcare Commission it was clearly impossible for it to be involved with such commercial enterprise, and the complainant advised the agency accordingly and considered the matter closed. The complainant's colleagues also withdrew their involvement.

The complainant was surprised therefore to discover that the project had continued and developed into a one day meeting 'Getting the most of MINAP' and with promotional material clearly emphasising a link with the MINAP project. The complainant provided a two page document headed 'Best practice seminars in using MINAP to improve local cardiac care' as an example of the material involved which he alleged had linked the companies sponsoring the meeting with MINAP. The item included the sentence 'The workshop is based on a new toolkit of best practice developed in association with the MINAP Steering Committee and local stakeholders'. As far as the MINAP steering committee was concerned this was false. An association was being made with MINAP – a mainstream and well regarded national project – and the commercial activities of these companies. No association existed and the complainant repudiated any involvement with this project. In Module 3 of the meeting there was to be feedback for the MINAP steering committee. MINAP had never solicited any feedback, nor had it received any. MINAP did not want to be associated with these activities and objected to its name being used in association with meetings sponsored by these pharmaceutical companies.

The complainant was concerned that:

- MINAP's good name had been used to commercial advantage, without permission and against the wishes of the MINAP steering group;
- these activities might be considered a form of disguised promotion;
- any suggestion in the promotional literature that MINAP was involved with this project was knowingly false and misleading;
- this activity had an adverse impact on MINAP and its relations with the very wide group of individuals who supported it; MINAP had its

own agenda of information and advice that it wished to impart ie by means of regional visits, and this was being subverted by these meetings.

The Panel noted that the complaint was about a series of meetings sponsored by Sanofi-Aventis and Bristol-Myers Squibb entitled 'Getting the most out of MINAP' although the complainant focussed on the arrangements for one of those meetings. According to the companies the meetings were designed to facilitate improvements in the quality of patient care through the better use of the MINAP audit tool. The meeting content and tool kit was developed by the companies' agency. The Panel did not consider that the companies were prohibited in arranging meetings about MINAP but such meetings had to comply with the Code. It was an established principle that the companies were responsible under the Code for the activities of agencies or other parties acting on their behalf.

The Panel noted the parties' submissions about the development of the toolkit and meeting programme. All agreed that initially the MINAP steering committee and the agency had talked about the meeting programme but that MINAP had subsequently stated that it did not want to have any further involvement with it. Regional MINAP staff also withdrew from the project. The companies submitted that they then took corrective measures to ensure that their material did not reflect an association with MINAP. However due to an error an old invitation was sent by the companies' agency to the meetings administrator who in turn sent it to invitees.

The invitation provided by the complainant was entitled 'Best practice seminars in using MINAP to improve local cardiac care. Getting the most out of MINAP'. A highlighted box, above the agenda, explained that the toolkit of best practice was developed in association with the MINAP steering committee and local MINAP stakeholders. 'Module 3: MINAP in practice' listed as its final bullet point 'Feedback for MINAP steering group'. The Panel considered that the invitation gave a misleading impression of the positive involvement of the MINAP steering committee and suggested that the toolkit was endorsed or otherwise approved by it. The Panel noted that whilst, at the request of MINAP, delegates were told at the outset of each meeting that the programme was not associated with the MINAP steering committee this was not sufficient to correct the otherwise misleading impression given by the invitation. The misleading impression was compounded by the wording of the declaration of sponsorship which explained that 'The toolkit development and workshop is sponsored by Bristol-Myers Squibb Pharmaceuticals Ltd and Sanofi-Aventis'. This implied that the companies' role was limited to financial support which was not so. The meetings and toolkit were in effect developed by the companies, via their agency in consultation with others. High standards had not been maintained. A breach of the Code was ruled. The Panel did not consider that the invitation brought discredit upon

and reduced confidence in the pharmaceutical industry.

The Panel noted that in subsequent invitations the reference to the role of MINAP and feedback had been removed. The Panel noted the agenda consisted of three modules: MINAP in the NHS, achieving the benefits and MINAP in practice. Copies of the presentations were provided and these discussed MINAP data under the module headings. There was no product specific material nor were there any exhibition stands at the meetings. The Panel considered that there was no evidence before it to indicate that the meetings were promotional and disguised in this regard. High standards had been maintained and no breach of the Code was ruled.

The Myocardial Infarction National Audit Project (MINAP) complained about the activities of an agency working on behalf of Sanofi-Aventis and Bristol-Myers Squibb, in particular, an invitation to a meeting (ref PLA06/1806).

COMPLAINT

The complainant noted that MINAP collected and analysed data on acute myocardial infarction from all acute hospitals in England and Wales. It had existed since 2000 and was now one of the world's largest audits of myocardial infarction. It was funded by the Healthcare Commission. Involvement with MINAP was mandatory for acute hospitals and MINAP analyses were used to measure hospital performance and as evidence of collaboration in national audit by the Healthcare Commission.

MINAP had a strong presence within the cardiac community and was widely recognised as a very successful long term national project which had resulted in major improvements in cardiac care. It was the end product of many years' hard work, and was highly respected as a source of national data on care for acute myocardial infarction. MINAP had never solicited support from industry; it was the view of the MINAP steering group that MINAP should have no involvement with the pharmaceutical industry.

The complainant stated that in summer 2006 a member of the MINAP steering group told him about a local collaboration in which she and a colleague were involved with Bristol-Myers Squibb which, in essence, involved development of a toolkit to assist hospitals make the best use of MINAP data. At the time this was a local development that the complainant's colleagues saw might be useful. The complainant understood that the cost was to be funded by an unrestricted educational grant from Bristol-Myers Squibb.

The complainant stated that as the general concept was of interest he had invited his colleague to present the work to the MINAP steering group, and this presentation received the (minuted) advice that she should proceed with great caution with any involvement with industry, and that MINAP itself would not become directly involved. Nevertheless, on the basis that Bristol-Myers Squibb would support the

development of the toolkit for the complainant's colleagues, he met the agency which was involved in developing the toolkit on behalf of Bristol-Myers Squibb, in order to hear more of its proposals. This consisted of developing the toolkit – on the basis of ideas provided locally by the complainant's colleagues – and presenting this work at a series of seminars involving clinicians, nurses, audit staff, and cardiac network staff throughout the country. It was stated by the agency that funding was unrestricted. After the meeting the complainant's colleagues had misgivings about the direction that the project was moving, and in particular it became clear that support was not unrestricted and that they were going to be working on an enterprise which had clear commercial involvement and which would involve promotion, either directly or indirectly, of relevant pharmaceutical products.

The complainant submitted that as MINAP was a national project funded by the Healthcare Commission it was clearly impossible for it to have any involvement with such commercial enterprise, and he advised the agency accordingly and considered the matter closed. The complainant's colleagues also withdrew their involvement.

The complainant was surprised therefore to discover that the project had continued and developed into a one day meeting 'Getting the most of MINAP' and with promotional material clearly emphasising a link with the MINAP project. The complainant provided a two page document headed 'Best practice seminars in using MINAP to improve local cardiac care' which was an example of the material involved which he alleged had linked the companies sponsoring the meeting with MINAP. The item included the sentence 'The workshop is based on a new toolkit of best practice developed in association with the MINAP steering committee and local stakeholders'. As far as the MINAP Steering Committee was concerned this was false. An association was being made with MINAP – a mainstream and well regarded national project – and the commercial activities of these companies. No association existed and the complainant repudiated any involvement with this project. In Module 3 of the meeting (shown in the item) it was stated that there was to be feedback for the MINAP steering committee. MINAP had never solicited any feedback, nor had it received any. MINAP did not want to be associated with these activities and objected to its name being used in association with meetings sponsored by these pharmaceutical companies.

The complainant was concerned that:

- the good name of MINAP had been used to commercial advantage, without permission and against the wishes of the MINAP steering group;
- these activities might be considered a form of disguised promotion;
- any suggestion in the promotional literature that MINAP was involved with this project was knowingly false and misleading;
- this activity had an adverse impact on MINAP and its relations with the very wide group of individuals who supported it; MINAP had its own

agenda of information and advice that it wished to impart ie by means of regional visits, and this was being subverted by these meetings.

When writing to the companies the Authority asked them to respond in relation to Clauses 2 and 9.1 of the Code.

RESPONSE

Sanofi-Aventis and Bristol-Myers Squibb submitted that the 'Getting the most out of MINAP' meetings programme sponsored by them and delivered on their behalf by their agency was a series of educational meetings designed to help health professionals who had to capture and work with MINAP data. The meetings were offered to health professionals within cardiac networks who acted as partners in the subsequent delivery of the local programme. Delegates included staff from ambulance services, acute hospital trusts, cardiac networks and primary care trusts (PCTs).

The companies submitted that the meetings were non-promotional and hence there was no product mentioned in the agenda or content of the meeting, neither were there any promotional stands at the event. The meetings aimed to facilitate improvements in the quality of patient care through the better use of the MINAP audit tool.

The companies submitted that, as stated by the complainant and during the development of the meeting programme, their agency had talked with members of the MINAP steering group and the complainant. During this dialogue the companies were advised that MINAP did not want any further involvement with their programme and so corrective measures were taken to ensure that materials did not reflect an association with MINAP. These changes were undertaken prior to the first local meeting in this programme (flyer provided).

The companies submitted that further, on the advice of MINAP, they undertook to verbally communicate at the outset of each meeting that the programme was not associated with the MINAP steering group. A senior officer of MINAP had also presented at one of the subsequent meetings.

The companies explained the approach taken in the organisation of the particular meeting referred to by the complainant:

- About ten weeks before the meeting took place the companies' local Healthcare Manager approached a cardiac network director and explained the objectives and programme content of the meeting so as to gauge initial interest and where appropriate identify potential areas for local focus.
- Following this initial meeting, the agency contacted the cardiac network director to clarify the programme content and agree on local issues relating to MINAP that needed to be considered.

For the region this included how to improve the quality of data in MINAP, agreement on provisional dates and the venue for the meeting, agreement on any local presenters and the identification of a network administrator who then emailed potential delegates with an approved flyer. In this regard the companies acknowledged that a previously approved version of the flyer was erroneously sent by the agency to the administrator.

- Delivery of actual event: arrangements for the venue, catering and other logistics were co-ordinated either by the companies or the agency, in accordance with the Code. The meeting was non-promotional. There were no promotional stands at the event, neither was there any other form of promotional activity at the event.

The companies provided copies of the materials relating to the meeting.

The companies submitted that the flyer used for the meeting was not the most up-to-date version as it had been superseded by one developed earlier in preparation for the first local meeting of this programme. The changes in the amended material had addressed the complainant's concerns as reference to MINAP's involvement in the development of this programme and feedback being given to the MINAP steering group had been removed.

The companies submitted that it was unfortunate that the obsolete version of the flyer was used instead of the updated document. In order to avoid this happening again, the companies had asked its agency to destroy any previous versions of materials that it might have which had been prepared for these meetings. The agency confirmed on 9 August that this had been done.

Specific concerns of complainant

- 1 'That the good name of MINAP had been used to commercial advantage, without permission and against the wishes of the MINAP Steering Group'

The companies reassured the Authority and MINAP that the main objective of the meetings programme was to ensure optimal local use of the MINAP audit tool, to ultimately lead to enhancements in patient care. This type of educational meeting was analogous to provision of education to local stakeholders on optimal implementation of other types of national, government-led initiatives such as National Institute for Health and Clinical Excellence (NICE) guidelines or the General Medical Services (GMS) contract

The companies reiterated that updated materials addressed the issues raised by the complainant and did not refer to any involvement of the MINAP group in the development of the programme or to feedback being given to the MINAP steering group.

Further, on the advice of MINAP, the companies, at the beginning of each meeting, verbally communicated

that the programme material was not directly associated with the MINAP steering group and that no association could be made subsequently. This disclaimer was communicated at the beginning of the meeting in question; the companies had written confirmation that this had happened at the meeting in question.

- 2 'That these activities might be considered a form of disguised promotion'

The companies reiterated that the meeting was non-promotional with no mention of product and no promotion either at the meeting or during any activities surrounding its preparation. Also, the companies reassured the Authority and MINAP steering group that this programme had been set up as a support to local cardiac networks in order to improve their understanding and use of MINAP. The main aim of these meetings was to work in partnership with local networks to enhance patient care through optimising the use of an existing national audit tool.

- 3 'That any suggestion in the promotional literature that MINAP had any involvement with this project was knowingly false and misleading'

The companies reiterated that all materials were non-promotional and any mention of involvement of the MINAP steering group in the development of this programme had been removed after communication with it. The flyer provided by the complainant was used in error on this occasion. As mentioned above, the companies had also undertaken to clearly communicate at each meeting that the MINAP group was not involved in the development of these meetings during the introduction at each meeting.

- 4 'That this activity had an adverse impact on MINAP and its relations with the very wide group of individuals who supported it'

The companies submitted that they stood behind the quality and non-promotional nature of this programme and sincerely regretted any error or misunderstanding that might have occurred.

The companies submitted that the meetings were intended as a facilitated discussion forum for MINAP users and/or health professionals familiar with the system in order to increase their knowledge on the use and potential implications of MINAP at local level, with the end objective of enhancing patient care through optimising use of this audit tool. They were also a good opportunity for sharing best practice on the use of MINAP (ie how to improve data collection and quality). It was important to clarify that MINAP software was not used during the meetings and all the materials used were developed by the agency on behalf of the companies.

In summary, the companies wished to reassure both the Authority and MINAP that this meeting was non-promotional and carried out in good faith to enhance understanding of MINAP in order to ultimately enhance patient care.

PANEL RULING

The Panel noted that the complaint was about a series of meetings sponsored by Sanofi-Aventis and Bristol-Myers Squibb entitled 'Getting the most out of MINAP' although the complainant focussed on the arrangements for one of those meetings. According to the companies the meetings were designed to facilitate improvements in the quality of patient care through the better use of the MINAP audit tool. The meeting content and tool kit was developed by the companies' agency. The Panel did not consider that the companies were prohibited from arranging meetings about MINAP but such meetings had to comply with the Code. The Panel noted that it was an established principle that the companies were responsible under the Code for the activities of agencies or other parties acting on their behalf.

The Panel was concerned that the invitation to the meeting in question provided by the complainant differed from that provided by the companies although each bore the same reference number. The highlighted box and relevant part of the agenda however were identical. The Panel made its ruling on the basis of the invitation provided by the complainant.

The Panel noted the parties' submissions about the development of the toolkit and meeting programme. All agreed that initially the MINAP steering committee and the agency had talked about the meeting programme but that MINAP had subsequently stated that it did not want to have any further involvement with it. Regional MINAP staff also withdrew from the project. The companies submitted that they then took corrective measures to ensure that their material did not reflect an association with MINAP. However due to an error an old invitation was sent by the companies' agency to the meetings administrator who in turn sent it to invitees.

The invitation provided by the complainant was entitled 'Best practice seminars in using MINAP to improve local cardiac care. Getting the most out of MINAP'. A highlighted box, above the agenda, explained that the toolkit of best practice was developed in association with the MINAP steering

committee and local MINAP stakeholders. 'Module 3: MINAP in practice' listed as its final bullet point 'Feedback for MINAP steering group'. The Panel considered that the invitation gave a misleading impression of the positive involvement of the MINAP steering committee and suggested that the toolkit was endorsed or otherwise approved by it. The Panel noted that whilst, at the request of MINAP's deputy clinical director, delegates were told at the outset of each meeting that the programme was not associated with the MINAP steering committee, this was not sufficient to correct the otherwise misleading impression given by the invitation. The misleading impression was compounded by the wording of the declaration of sponsorship which explained that 'The toolkit development and workshop is sponsored by Bristol-Myers Squibb Pharmaceuticals Ltd and Sanofi-Aventis'. This implied that the companies' role was limited to financial support which was not so. The meetings and toolkit were in effect developed by the companies, via their agency in consultation with others. High standards had not been maintained. A breach of Clause 9.1 was ruled. The Panel did not consider that the invitation brought discredit upon and reduced confidence in the pharmaceutical industry. No breach of Clause 2 was ruled.

The Panel noted that in subsequent invitations the reference to the role of MINAP and feedback had been removed. The Panel noted the agenda consisted of three modules: MINAP in the NHS, achieving the benefits and MINAP in practice. Copies of the presentations were provided and these discussed MINAP data under the module headings. There was no product specific material nor were there any exhibition stands at the meetings. The Panel considered that there was no evidence before it to indicate that the meetings were promotional and disguised in this regard. High standards had been maintained. No breach of Clause 9.1 was ruled. Accordingly, the Panel ruled no breach of Clause 2 on this point.

Complaint received	2 August 2007
Cases completed	25 September 2007
