

# GENERAL PRACTITIONER v NORGINE

## Invitation to a meeting

A general practitioner alleged that the £250, along with hospitality and transport, offered to him by Norgine to attend a 'Managing Constipation Movicol Regional Advisory Forum' was excessive. It simply did not seem tenable that the meeting was necessary or even conceivably of any business value to the company. In the complainant's view this was merely an attempt to pay doctors to promote Movicol using a loophole in the Code.

The Panel noted that the invitation to the meeting in question stated that the honorarium was in recognition of 'your time and input at the meeting'. The invitation stated that Norgine wanted to hear the views of health professionals on the management of chronic constipation and faecal impaction. The company would review current prescribing patterns and discuss any relevant local issues. The Panel considered that the invitation could have been clearer as to the exact nature of the meeting.

The agenda was sent once the invitation was accepted. The meeting would start at 6.30pm with a buffet dinner and then run from 7pm to 9pm. It included an introduction to Norgine (10 minutes), the evidence base for treating constipation (30 minutes) and a review of the therapy area and the laxative market (20 minutes). The latter two sessions included a facilitated group discussion. The final session 'Developing a local action plan: what do Norgine need to be doing?' was a group discussion of 45 minutes.

The report for a similar meeting showed that the event had been interactive. Attendees had identified issues which would be relevant to Norgine on a national basis. The report included a number of action points for the local Norgine team to follow up.

The Panel noted that the feedback form for the meeting at issue seemed at odds with the purpose of the advisory board. In the Panel's view the main benefit of an advisory board should be to the sponsoring company and not to the delegates. Feedback was requested to ensure that Norgine had met the attendee's needs and expectations. It included questions on the educational content of the meeting and the relevance and interest of the sessions. Delegates were asked whether their management of chronic constipation and faecal impaction was likely to change as a result of the meeting and to identify key take home messages. The Panel considered that in the context of an advisory board such questions might be inappropriate. The context in which the form was presented to the attendees would be important.

Nonetheless the Panel did not consider that the form on its own rendered the meeting inappropriate.

On balance the Panel considered that the arrangements for the meeting were not unacceptable. It was acceptable to pay doctors to attend advisory board meetings. The Panel ruled no breaches of the Code.

The Panel did not accept that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and ruled accordingly.

A general practitioner complained about an invitation (ref MO/07/1118 March 2007) to a 'Managing Constipation Movicol Regional Advisory Forum' to take place in Scotland on 30 May, sent by Norgine Pharmaceuticals Ltd.

## COMPLAINT

The complainant alleged that the fees offered to attend the advisory board were excessive at £250, along with hospitality and transport. It simply did not seem tenable that the meeting was necessary or even conceivably of any business value to the company.

In the complainant's view this was merely an attempt to pay doctors to promote Movicol using a loophole in the Code.

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

## RESPONSE

Norgine explained that Movicol (macrogol 3350 plus sodium chloride, sodium bicarbonate, and potassium chloride) was a product for chronic constipation and faecal impaction. Despite overwhelming evidence that had accumulated over the past few years, showing that macrogol laxatives like Movicol were more effective and better tolerated than older laxatives, such as lactulose and ispaghula husk, the older laxatives still dominated the market, and Movicol had less than half the market share of lactulose.

In addition, pharmacoeconomic studies showed that Movicol was a dominant treatment compared to lactulose ie not only was Movicol more effective than lactulose, but it also reduced costs. Norgine

decided to convene a number of regional advisory boards primarily to assess if there were any local issues that prevented Movicol achieving a market share commensurate with the current evidence base.

It was clearly essential for Norgine to present the current evidence at the meeting so that all the delegates had the same level of knowledge in order for them to contribute optimally to the meeting.

According to Norgine's advisory board guidelines (copy provided), the advisory board should have a clear objective in relation to the advice required, and should be set up to allow the objective to be met. The objective of any individual meeting determined: the selection of members, who were selected individually on the basis of their knowledge and experience; the number of members, who should represent the different groups managing the disease of interest, and was limited to allow each member to make a meaningful contribution and the number of meetings, dependent on the different management of the disease in different regions.

In practice, the regional manager asked their local sales representatives and NHS liaison managers to nominate possible delegates. Norgine had invited 32 delegates from the local area and planned to have 10 attendees on the night. This relatively small number was designed to ensure that all delegates had a chance to make a significant contribution to the meeting. Lists of the invitees' and attendees' names and addresses would be available after the meeting had taken place. This was the only regional advisory forum planned to be held in Scotland.

The invitations were all sent directly from head office: representatives were not given letters to hand out.

The delegates were a mix of GPs managing the disease of interest, consultants from the local hospitals, PCT representatives (eg pharmacists) and one or two continence advisors who were experienced in managing constipation and faecal incontinence. It was important that all the delegates were knowledgeable in the area, as Norgine was seeking their advice on local prescribing guidelines for constipation (if any), the reason that Movicol was not prescribed first line, what Norgine could do to change prescribing habits in line with the current evidence and any other issues considered important.

In terms of Norgine's advisory board guidelines, it was acceptable to pay advisory board members an honorarium, which should appropriately reflect the amount of time and effort required, and was in keeping with usual professional rates. For the meeting in question £250 (ie £125/hour) was very reasonable and certainly not excessive compared with BMA rates of over £200/hour for private consultation or report writing. Similarly Norgine would pay less per mile than the BMA currently

stated. The same fee was payable irrespective of the professional standing of the delegate ie consultants were paid the same as GPs. The invitation made it clear that the honorarium was in recognition of the individual's time spent on, and input to, the meeting. No work prior to the meeting was asked for. The honorarium did not include any travelling time, nor did it account for the fact that the meeting took place outside of normal working hours. The advisory board was run for the benefit of the company, with advice on local prescribing practices provided as a professional service, in the same way that professional advice and services were provided to patients on health matters. The meetings were very interactive. The delegates participated in every session, asking questions, giving their opinions, and offering advice.

The hospitality for the forum would consist of a buffet dinner, which would last half an hour. No alcohol would be provided. If delegates required overnight accommodation because they had far to travel, this would be provided at the hotel by Norgine. The venue would be a local 4 star hotel.

Norgine stated that two national advisory boards were held in England in 2006 and one in 2007.

Copies were provided of the presentations used at the Movicol regional advisory forum in Ireland in April, which would be adapted for the meeting in Scotland. As the Scotland meeting was scheduled for May, Norgine had not yet finalised the presentations for the meeting. The meeting in Ireland would not be identical to the meeting in Scotland, as it referred to Irish market shares and Irish products, but it gave a reasonable idea as to what would be presented in Scotland.

Norgine submitted that the meeting summary report of a previous Movicol regional advisory forum held in England in February, clearly illustrated the level of lengthy and interesting discussions, as well as the sound advice and feedback on the local situation that was provided to the company. The actions noted clearly demonstrated that these regional advisory forums were of significant advisory value to Norgine. In addition to a meeting summary report, an audio recording was also made of all advisory meetings which reinforced the genuine advisory nature of these meetings.

In conclusion, Norgine believed that the regional advisory forum to be held in Scotland was a genuine advisory meeting of real business value to Norgine, and did not amount to offering a pecuniary advantage to induce the prescription of a medicine. It was made clear that the honorarium offered was for the input into the meeting expected from the delegates, and the amount was reasonable for providing input to a meeting held outside normal working hours.

Norgine also believed that the arrangements for the meeting were of a high standard. This was reflected

*inter alia* by the fact that a limited number of delegates were invited, and all invitations were personal invitations from the medical director of Norgine. Also Norgine believed that appropriate subsistence was to be provided to delegates, and the venue was not a lavish hotel, which would in itself be attractive to delegates.

Norgine regretted that the GP in question would not be attending the meeting. If he or she were to attend, Norgine was confident that they would be reassured about the genuine advisory nature of the meeting, and that the honorarium was commensurate with the input expected from them.

In response to a request for further information Norgine stated that it had already held one Movicol regional advisory forum this year and two others were planned, including the meeting that was the subject of this complaint. Approximately ten delegates were expected to attend each meeting, giving a total of thirty for the three meetings.

The success of the Movicol national advisory boards was measured by the qualitative outputs from these three meetings (see below) as reflected in the meeting summary reports. Direct quotes from these meeting reports were as follows:

‘The multidisciplinary group provided a well rounded discussion and valuable insight in to the different issues effecting each of the delegates’ specialities’. (April 2006)

‘The meeting was a great success with some lengthy and interesting discussion, and the delegates offering sound advice and feedback to Norgine’. (July 2006)

‘This was a highly successful meeting, with good discussion and a well engaged group..... The second Movicol National Advisory Board centred around updating the delegates on the progress of recommendations made in the first meetings, as well as discussion around the key challenges in patient management and the development of constipation in patient management and the development of constipation care pathways in both primary and secondary care’. (December 2006).

It was also inevitable that the Norgine personnel present at the advisory board meeting formed their own views as to how beneficial the meeting had been to the company. Further meetings would not have taken place had senior managers not been convinced that these national meetings were a success in respect of the value of the advice they delivered to Norgine. No other metrics, including quantitative measures, were used to evaluate these meetings, nor would they be for the two further meetings planned.

Delegates to the national meetings were drawn from all parts of the UK. Participants were recruited on the basis of their expertise and experience rather

than their geographic location.

As far as the specific recommendations which led to the plan to have regional advisory boards was concerned, the following statement appeared in the meeting summary report of the meeting in July 2007:

‘[A named person] updated the group on the progress Norgine has made with the recommendations from the group, including the Regional Advisory Forums, patient and professional group liaison, and educational materials and meetings’.

## PANEL RULING

The Panel considered that there was a difference between holding a meeting for health professionals and employing them to act as consultants. It was acceptable for companies to arrange advisory board meetings and the like and to pay health professionals and others for advice on subjects relevant to the products they promoted. Nonetheless the arrangements for such meetings had to comply with the Code. The requirements as to hospitality being of a reasonable standard etc, as set out in Clause 19 of the Code had to be followed. The company must be able to justify the number of meetings held. The choice and number of delegates should stand up to independent scrutiny; each should be chosen according to their expertise such that they would be able to contribute meaningfully to the purpose and expected outcomes of the meeting. The number of delegates at a meeting should be limited so as to allow active participation by all. The agenda must allow sufficient time for feedback and input by the delegates. Invitations to participate in an advisory board meeting should clearly state the purpose of the meeting, the expected role of the invitees and the amount of work to be undertaken; it should be clear that any honorarium offered was a payment for such work and advice.

The invitation to the meeting in question stated that the honorarium was in recognition of ‘your time and input at the meeting’. The invitation stated that Norgine wanted to hear the views of health professionals on the management of chronic constipation and faecal impaction. The company would review current prescribing patterns and discuss any relevant local issues. The Panel considered that the invitation could have been clearer as to the exact nature of the meeting.

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what do Norgine need to be doing?’ was a group discussion of 45 minutes. The slides for the meeting held in Ireland gave a breakdown of the laxative market as well as comparing Movicol, Lactulose and Fybogel.

From the report for a recent Regional Advisory Forum it appeared that the meeting had been interactive with comments in the report attributed to various attendees. Issues had been identified by the attendees which would be relevant to Norgine on a national basis. The Panel noted that the meeting report included a number of action points for the local Norgine team to follow up.

The Panel noted that the feedback form for the meeting at issue seemed at odds with the purpose of the advisory board which was to provide Norgine with information. In the Panel’s view the main benefit of an advisory board should be to the sponsoring company and not to the delegates. Feedback was requested to ensure that Norgine had met the attendee’s needs and expectations. It included questions on the educational content of the meeting and the relevance and interest of the sessions. Delegates were asked whether their

management of chronic constipation and faecal impaction was likely to change as a result of the meeting and to identify key take home messages. The Panel considered that in the context of an advisory board such questions may be inappropriate. The context in which the form was presented to the attendees would be important. Nonetheless the Panel did not consider that the form on its own rendered the meeting inappropriate.

On balance the Panel considered that the arrangements for the meeting were not unacceptable. It was acceptable to pay doctors to attend advisory board meetings. The Panel ruled no breach of Clause 18.1 of the Code and thus no breach of Clause 9.1.

The Panel did not accept that the circumstances warranted a ruling of a breach of Clause 2 which was used as a sign of particular censure and ruled accordingly.

<b>Complaint received</b>	<b>26 March 2008</b>
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<b>Cases completed</b>	<b>25 May 2008</b>
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