

# CONSULTANT RHEUMATOLOGIST v ROCHE

## Meeting at the Royal College of Physicians

A consultant rheumatologist complained about a meeting broadcast on the Internet from the Royal College of Physicians (RCP) on 19 June, which had been sponsored by Roche.

The complainant had not had a satisfactory reply from the RCP to her enquiries about Roche's role in sponsoring the meeting which in essence was about what to do with patients with inflammatory arthritis who had failed anti-TNF therapy. The options presented were switching to abatacept or to rituximab (Roche's product MabThera). Since abatacept had not been approved by the National Institute of Health and Clinical Excellence (NICE), it was effectively unavailable in the UK, hence the speakers were only promoting the use of rituximab. The complainant submitted that the speakers were paid by the RCP but she had not had an answer to emails about payment to the RCP by Roche. The complainant did not know whether the company's involvement was appropriate; it was declared, but the complainant did not think that the RCP should be effectively promote a medicine in which it had a financial interest when there were other clinical options, not mentioned at the meeting, such as changing or switching medicines for these patients.

The detailed response from Roche is given below.

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

The Panel noted that Roche's representatives had promoted the webcast by the use of flyers which incorporated the logos of the RCP and Roche on the front cover together with the statement 'Sponsored by an educational grant from Roche Products Limited'. A briefing note instructed representatives to encourage as many customers as possible to log on 'live' or to view the archived event over the next 12 months. In the Panel's view, the use of representatives to distribute flyers brought the webcast within the scope of the Code.

The Panel noted that Roche's sponsorship of the webcast was obvious at the outset on both the flyer and the webcast. It appeared that the complainant was more concerned about the role of the RCP. The agreement regarding the live webcast stated that Roche could suggest topics and speakers but final approval of the programme rested with the RCP. The agreement required that Roche must not contact the speakers or discuss the programme with them prior to or during the event. The speakers were responsible for exercising full control over the lectures and discussions and any content therein. Roche could have no involvement in that process.

The Panel had some concerns about the webcast. Clearly the topic 'Identifying and Managing Anti-TNF Inadequate Responders in RA' was relevant to MabThera as that was a possible alternative treatment choice for such inadequate responders. The speakers would presumably know which company had sponsored the webcast. The presentation on 'Managing anti-TNF inadequate responders' had included favourable statements about rituximab. Other medicines such as infliximab, etenercept and abatacept were also referred to. In theory products could be used irrespective of approval by NICE. In summing up the Chairman had specifically referred to rituximab. Nonetheless the Panel did not consider that the sponsorship arrangements were unreasonable; the RCP had the final approval of the programme and speakers. The Panel did not consider that Roche's involvement was inappropriate as alleged. The webcast was clearly sponsored by Roche and so was not misleading in that regard. No breach of the Code was ruled.

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### COMPLAINT

The complainant stated that she had not had a satisfactory reply to her enquiries from the RCP about Roche's role in sponsoring the meeting which in essence was about what to do with patients with inflammatory arthritis who had failed anti-TNF therapy. The options presented were switching to abatacept or to rituximab [Roche's product MabThera]. Since abatacept had not been approved by the National Institute of Health and Clinical Excellence (NICE), it was effectively unavailable in the UK, hence the speakers were only promoting the use of rituximab. The complainant

submitted that the speakers were paid to speak by the RCP directly but she had not had an answer to two emails about payment to the RCP by Roche. The complainant did not know if the company's involvement was appropriate or not, certainly it was declared, but the complainant did not think that the RCP should be effectively promoting the use of a particular medicine in which it had a financial interest when there were other clinical options such as changing or switching medicines for these patients which were not mentioned at the meeting.

When writing to Roche, the Authority asked it to respond in relation to Clauses 2, 7.2, 9.1 and 19 of the 2006 Code. The case would be considered under the 2008 Constitution and Procedure.

## **RESPONSE**

Roche stated that the complaint concerned the 'RCPLive' Internet lecture 'Identifying and Managing Anti-TNF Inadequate Responders in RA [rheumatoid arthritis]' which had been launched recently on the RCPLive website.

Roche noted that the complainant was dissatisfied about a lack of response to her enquiries from the RCP, the involvement of the RCP in holding meetings that focussed on a specific treatment, or class of treatments and the receipt of sponsorship by the RCP from Roche for this meeting.

Roche believed that the first two matters of complaint were aimed at the RCP and as such fell outside of the scope of the Code. Regarding the third, Roche believed the arrangements for the sponsorship were appropriate.

Roche explained that it was approached by a third party acting on behalf of the RCP to sponsor the RCPLive lecture on rheumatology. The sponsorship was subject to the terms and conditions of the contract, which was provided. These terms and conditions were in line with Roche's obligation to be clear and transparent as to its involvement in the sponsorship of this lecture. It clearly established the roles and responsibilities of both Roche and the third party in the implementation of the project.

Roche did not select the speakers at the meeting. Although the company was able to suggest topics and speakers, the final selection and approval of the programme rested with the RCP.

Roche did not see the presentations. The contract stated that 'The sponsor must not make contact with speakers or discuss the programme content with them prior to or during the event'. There was no transcript of the meeting available. The lecture could be viewed directly from the RCPLive website.

The approval and payment of sponsorship to the RCP followed the appropriate internal operating procedure for medical and education goods and services for which the paperwork was provided.

In summary Roche believed that the sponsorship of the RCPLive Internet lecture in rheumatology was appropriate and followed the procedures set out in both internal process and the Code.

Roche believed that the issues the complainant raised were directed at the RCP and her perception of the activities with which the RCP should involve itself.

## **FURTHER RESPONSE FROM ROCHE**

In response to a request from the Panel for further information, Roche stated that its representatives had advertised the webcast via a flyer, as allowed by the RCPLive initiative, which gave guidance on flyer production. The use of this RCP-approved flyer was briefed to the representatives via email.

Roche reiterated that it had no influence on either the speakers or the content of their presentations. Roche did not see the presentations prior to them being broadcast. The company had made no use, nor did it intend to, of any materials from the webcast lecture in any format.

## **PANEL RULING**

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

The Panel noted that Roche's representatives had promoted the webcast by the use of flyers. The RCP guidance on flyer production referred to the need for them to be approved by the RCP prior to use as well as setting out requirements for content and layout. The flyers incorporated the logos of the RCP and Roche on the front cover together with the statement 'Sponsored by an educational grant from Roche Products Limited'. Inside the flyer readers were given the programme for the webcast and instructions as to how to participate. Representatives were instructed to encourage as many customers as possible to log on 'live' or to view the archived event over the next 12 months. The one page briefing was sent by the MabThera brand manager and incorporated the brand logo in the top right-hand corner. In the Panel's view, the use of representatives to distribute flyers brought the webcast within the scope of the Code.

The Panel noted that Roche's sponsorship of the webcast was obvious at the outset on both the flyer and the webcast. It appeared that the complainant was more concerned about the role of the RCP. The agreement between Roche and the third party referred to a live webcast on rheumatoid arthritis. Roche could suggest topics and speakers but final approval of the programme rested with the RCP. The agreement required that Roche must not contact the speakers or discuss the programme with them prior to or during the event. The speakers were responsible for exercising full control over the lectures and discussions and any content therein. Roche could have no involvement in that process.

The Panel had some concerns about the webcast. Clearly the topic 'Identifying and Managing Anti-TNF Inadequate Responders in RA' was relevant to MabThera as that was a possible alternative treatment choice for such inadequate responders. The speakers would presumably know which company had sponsored the webcast. The presentation on 'Managing anti-TNF inadequate

responders' had included favourable statements about rituximab. Other medicines such as infliximab, etenercept and abatacept were also referred to. In theory products could be used irrespective of whether or not they had been approved by NICE. In summing up the Chairman had specifically referred to rituximab. Nonetheless the Panel did not consider that the sponsorship arrangements were unreasonable; the RCP had the final approval of the programme and speakers. The Panel did not consider that Roche's involvement was inappropriate as alleged and ruled no breach of Clauses 9.1 and 19. The webcast was clearly sponsored by Roche and so was not misleading in that regard. No breach of Clause 7.2 was ruled. The Panel also ruled no breach of Clause 2; as that clause was used as a sign of particular censure and reserved for such.

<b>Complaint received</b>	<b>8 July 2008</b>
<b>Case completed</b>	<b>25 September 2008</b>

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