CASE AUTH/2598/4/13

CONSULTANT RHEUMATOLOGIST v ROCHE

Promotion of Mabthera

A consultant rheumatologist alleged that a talk about ANCA [anti-neutrophil cytoplasmic antibody]-associated vasculits (AAV), given at a national rheumatology conference, was excessively promotional and against the spirit of the Code. The talk was sponsored by Roche. Roche marketed Mabthera (rituximab) which was recently licensed for the treatment of two forms of AAV, but not for a third.

The complainant noted that the speaker repeatedly stated that he could not refer to rituximab and vasculitis, but that a subsequent speaker in another session would tell them all they needed to know.

The detailed response from Roche is given below.

The Panel noted that Roche had booked a 30 minute workshop at the conference. Guidelines from the organisers stated that the meeting space would be within the exhibition hall and that the session should be educational rather than promotional. The guidelines did not define either term. Examples of acceptable topics included, *inter alia*, educating delegates on a product. The Panel noted that such a presentation would satisfy the broad definition of promotion given in the Code. The Panel queried whether a trade exhibition hall was an appropriate space for a non-promotional presentation.

When Roche engaged the speaker to talk about AAV for rheumatologists it was a therapy area in which the company had no licensed medicine; a relevant licence was obtained for Mabthera the day before the presentation. The Panel noted that the speaker agreement, certified in January 2013, stated that the objective of the session was to increase the awareness of the presentation, diagnosis and management of the three forms of AAV amongst rheumatologists. It also stated that the presentation was to be non-promotional with no proactive mention of Mabthera. Two of the speaker's slides, however, referred to Mabthera and in addition, both parties agreed that the speaker had referred delegates to a subsequent session in the main conference programme where rituximab in AAV would be discussed. In the Panel's view the slides and speaker's comments meant that the presentation, although highly educational, was promotional. The presentation was delivered on the day after a licence was granted allowing the use of Mabthera in two forms of AAV. The speaker's final slide referred to the use of biologics in AAV without qualification and so appeared relevant to all forms of AAV. The Panel thus considered that the presentation implied that Mabthera could be used in all forms of AAV which was not in accordance with the terms of its marketing authorization and a breach of the Code was ruled.

The Panel noted that Roche had certified the speaker's slides whilst the licence for the use of Mabthera in AAV was pending. The Panel assumed that Roche would know that it would not include the third form of AAV. The Panel noted that although the speaker had requested that the final slide be retained, Roche should have ensured that, irrespective of his wishes, it had complied with the Code. Given its ruling above the Panel considered that high standards had not been maintained and a breach of the Code was ruled.

The Panel noted that as the meeting programme clearly stated that the session in question was associated with Roche, attendees would expect to hear about the sponsor's medicines. The session was not portrayed as a non-promotional event. In that regard the Panel did not consider that the promotional nature of the session had been disguised and no breach of the Code was ruled.

A consultant rheumatologist complained about a talk he/she attended at a national annual conference for rhematologists. The talk, sponsored by Roche Products Limited, was entitled 'ANCA [anti-neutrophil cytoplasmic antibody]-associated vasculitis for rheumatologists'. The complainant presumed that the speaker was paid by Roche to give the talk as he was a world expert in the field of vasculitis.

The indications for Mabthera (rituximab) included in combination with methotrexate to treat adult patients with severe active rheumatoid arthritis who had an inadequate response or intolerance to other disease modifying anti-rheumatic drugs (DMARD) including one or more tumour necrosis factor (TNF) inhibitor therapies. The day before the presentation, Mabthera was also licensed for use in combination with glucocorticoids, for the induction of remission in adult patients with severe, active granulomatosis with polyangitis (Wegener's) (GPA) and microscopic polyangitis (MPA). Both conditions were forms of ANCA-associated vasculitis. Mabthera was not licensed for a third form of ANCA-associated vasculitis ie eosinophilic granulomatosis with polyangitis (Churg Strauss Syndrome (CSS)).

COMPLAINT

The complainant stated that the speaker repeatedly stated that he was not allowed to mention rituximab, or the 'R' word in the context of vasculitis, because of the Code. He also stated that he would end the session early and urged everyone to attend the next timetabled session by his colleague which would tell them everything they needed to know about rituximab in vasculitis.

The complainant alleged that this was excessive

promotion of a product which went against the spirit of the Code.

When writing to Roche, the Authority asked it to consider the requirements of Clauses 3.2, 9.1 and 12.1 of the Code.

RESPONSE

Roche explained that the session in question was a new venture by the conference organisers as part of the 2013 meeting and slots were offered to potential sponsors. Roche booked the 11.00-11.30am slot on 23 April 2013, as part of its conference booking made on 5 September 2012. At the time of booking, information on the conference website confirmed that the session would be in a separate, sectioned off area of the exhibition hall. There was no prior knowledge of the detailed main session programme for that day; such detail was only available on the conference website from December 2012. A copy of the exhibition booking form was provided.

Roche confirmed with the organisers the non-promotional and educational expectation of the sessions, which were open to all delegates. Clarification was sought because the content as stated in the conference guidelines (copy provided) allowed for education on a product. The guidelines did not allow for the session to be advertised by the use of company flyers, however promotion of the session was permitted from the company stand and outside the session space at the allocated time.

As the session was non-promotional, Roche considered that it would have been inappropriate to promote the meeting from a promotional stand. Roche staff were thus briefed not to actively encourage attendance at this Roche organised session. A copy of the staff briefing slides was provided.

Roche chose the session topic "ANCA-associated vasculitis (AAV) for rheumatologists" as an area of continued unmet educational need, particularly since the diagnosis of AAV was complex and often missed by non-specialist rheumatologists. Roche was especially mindful of the pending outcome of the Mabthera licence submission for the indication of two forms of AAV. Due to this, even more care was taken to ensure the total non-promotional objectives of the session.

The speaker was engaged by Roche through a consultancy agreement to present on the topic of 'ANCA-associated vasculitis (AAV) for rheumatologists'. The agreement detailed the objective of the session: to increase awareness of the presentation, diagnosis and management of three forms of AAV. The agreement specified the non-promotional requirement for the presentation in four instances, and explicitly stated that no proactive mention of rituximab was to be made. The consultancy agreement was discussed with the speaker in February 2013 to ensure the objectives and non-promotional content of the presentation were clear. The speaker considered that rituximab should be discussed for completeness, however, Roche reiterated that rituximab should not be discussed as part of the presentation. The signed consultancy agreement and accompanying certificate were provided.

The speaker agreed to omit data slides on rituximab. However, he requested that a final summary slide which listed the clinical trials in AAV that had been conducted with a variety of biologics, including rituximab, be retained. The session slides were reviewed and approved by Roche, to confirm consistency with the directions provided in the consultancy agreement, factual accuracy, and that they complied with the Code. The slides and accompanying approval sign-off were provided.

Roche met the speaker immediately before the session started and he confirmed that he understood the non-promotional intent of the presentation and the requirement not to proactively mention rituximab. At the start of the presentation, he stated that he was not allowed to discuss rituximab as part of the presentation. He also stated once that there was a main program session where the rituximab trial data in AAV would be presented. The speaker's presentation did not finish early. A statement from a company employee detailing all interactions with the speaker and what he heard stated at the session was provided.

The main conference programme which followed Roche's session, ran seven parallel sessions. One of these sessions 'Biologics in connective tissue disease' presented three topics, one of which was 'Rituximab in ANCA-associated vasculitis (AAV)'. This topic was selected by the conference organisers.

The speaker considered that to discuss AAV without mentioning rituximab was unbalanced and therefore, he referred to the main conference programme session for those who wanted information on rituximab. A copy of an e-mail from the speaker confirming his opinion and reason for referencing the main session was provided.

In relation to Clause 3.2 Roche submitted that rituximab received a licence for two forms of vasculitis on 22 April 2013, therefore referring to rituximab in an educational session on AAV was not inconsistent with the particulars listed in the summary of product characteristics. As previously detailed, the session was designed to raise awareness of a disease area of high unmet medical education need, and therefore was organised as a non-promotional event, with no intent to promote or solicit any discussions on rituximab. Furthermore, the consultancy agreement confirmed the non-promotional objective of the presentation and the direction not to discuss rituximab. The session slides contained no promotional content. There was no promotion of the session from the stand or by company representatives.

Roche submitted that it had complied with Clause 20.1 as detailed in the signed consultancy agreement. Roche ensured that the content of the

session slides complied with both the consultancy agreement and Clause 3.2. The consultancy agreement explicitly stated that there was to be no proactive mention of rituximab, which was reinforced during the 13 February verbal briefing. Staff were briefed not to encourage attendance at the session. In Roche's view these steps demonstrated that there was no intent to use the session as 'teaser' advertising, as described in the supplementary information to Clauses 9.1 and 9.2. High standards were maintained during the planning and delivery of this session.

Roche submitted that its sponsorship of the session was declared in the conference program in accordance with Clause 9.10. Roche had no prior knowledge of the seven parallel program sessions that would follow the session at issue. The educational intent of the Roche session was detailed in the consultancy agreement, demonstrated in the session slides and was consistent with the non-promotional and educational objective as stipulated in the relevant conference guidelines. The materials and the activity were neither promotional in nature nor disguised in terms of Roche's involvement.

In conclusion Roche submitted that the session was non-promotional in accordance with the conference guidelines. The AAV session topic was a disease for which rituximab had a licensed indication. The speaker's reference to the main conference program session on the same topic, which followed the Roche sponsored session was not made repeatedly, and was done to complete the scientific content of his presentation. Roche concluded that there was no excessive promotion of rituximab at the session.

PANEL RULING

The Panel noted that Roche had booked the 30 minute workshop at the meeting. Guidelines from the organisers stated that the session would be based within the exhibition hall and that the content of the session should be educational rather than promotional. The guidelines did not define either term. Examples of acceptable topics included, *inter alia*, educating delegates on a product. The Panel noted that such a presentation would satisfy the broad definition of promotion given in Clause 1.2. The Panel queried whether a trade exhibition hall was an appropriate space for a non-promotional presentation.

Roche had engaged a speaker to talk about AAV for rheumatologists, a therapy area in which, when the speaker was engaged, Roche had no licensed medicine; a relevant licence was obtained for Mabthera the day before the presentation. The Panel noted that the speaker agreement, certified late January 2013, stated that the objective of the session was to increase the awareness of the presentation, diagnosis and management of GPA, MPA and CSS amongst rheumatologists. It also stated that the presentation was to be non-promotional with no proactive mention of Mabthera. Two of the speaker's slides, however, referred to Mabthera. One of the slides referred to cyclophosphamide plus corticosteroids and then mentioned rituximab in brackets (the Panel did not know the significance of this statement) and the final slide, which the speaker had argued to retain, was headed 'Biologics in ANCA associated vasculitis' and stated that for rituximab, *inter alia*, there had been 3 prospective trials and 4 case series. The following was also stated '2008 – 10 – Rituxvas and RAVE, non-inferiority, as effective in induction as cyclo but no decrease in toxicity'. In addition to the slides the Panel noted that both parties agreed that the speaker had referred delegates to a subsequent session, which was part of the main conference programme, where rituximab trial data in AAV would be discussed. In the Panel's view the slides and speaker's comments about rituximab and its use in AAV was sufficient to mean that the presentation, although highly educational, was promotional under the Code. The presentation was delivered on the day after a licence was granted allowing the use of Mabthera in two forms of AAV ie GPA and MPA. Mabthera was not licensed for use in the third form, CSS. The speaker's final slide referred to the use of biologics in ANCA associated vasculitis without qualification and so appeared relevant to all forms of AAV. The Panel thus considered that the presentation implied that rituximab could be used in all forms of AAV which was not in accordance with the terms of the Mabthera marketing authorization and a breach of Clause 3.2 was ruled.

The Panel noted that the speaker's slides had been certified by Roche on 11 and 12 April when the company had no licence for the use of Mabthera in ANCA associated vasculitis and although a licence application was pending, the Panel assumed that Roche would know that it would not include CSS. The Panel noted that although the speaker had requested that the final slide be retained, Roche should have ensured that, irrespective of the speaker's wishes, it had complied with the Code. Given its ruling above the Panel considered that high standards had not been maintained and a breach of Clause 9.1 was ruled.

The Panel noted that the meeting programme clearly stated that the session in question was associated with Roche. In that regard the Panel considered that delegates attending the session would expect to hear about the sponsor's medicines. The session was not portrayed as a non-promotional event. In that regard the Panel did not consider that the promotional nature of the session had been disguised and no breach of Clause 12.1 was ruled.

Complaint received **29 April 2013**

Case completed **21 June 2013**