CASE AUTH/2138/7/08

PUBLIC HEALTH PHYSICIAN v RECKITT BENCKISER HEALTHCARE

Gaviscon Advance journal advertisements

A public health physician complained about two advertisements for Gaviscon Advance (sodium alginate and potassium bicarbonate) issued by Reckitt Benckiser Healthcare and published in the BMJ.

The complainant stated that the advertisements presented data from *in-vitro* studies but made claims about expected *in-vivo* effects. The conclusions presented misled the reader because they made unsubstantiated claims about clinical situations that could not be reasonably extrapolated from the *in-vitro* data presented.

The detailed response from Reckitt Benckiser is given below.

Both abstracts, and therefore both advertisements, detailed *in-vitro* studies. The Panel noted that supplementary information to the Code stated that care must be taken with, *inter alia*, the use of data derived from *in-vitro* studies so as to not mislead as to its significance. The extrapolation of such data to the clinical situation should only be made where there was data to show that it was of direct relevance and significance. The Panel noted that it was a principle under the Code that claims related to the clinical situation unless clearly stated otherwise.

The advertisement entitled 'The Role for Liquid Alginate Suspension (Gaviscon Advance) in the Protection of the Oesophagus Against Damage by Bile in the Refluxate' featured a schematic diagram of a cell model used to assess diffusion of bile acids. Under the heading 'Conclusion' the first bullet point clearly referred to an *in-vitro* model. The third bullet point, however, stated '*In-vivo*, the mode of action of Gaviscon Advance is expected to give oesophageal protection from the damaging potential of bile acids'. The Panel noted Reckitt Benckiser's submission that it was not unreasonable to consider that Gaviscon Advance *might* [emphasis added] produce the same results *in-vivo* as *in-vitro*. The company had not produced any data to support this statement. In the Panel's view, the claim was based on assumption and together with the title of the advertisement suggested that Gaviscon Advance *would* [emphasis added] protect the oesophagus from damage by bile in the refluxate; the use of the wording 'expected to give' in the claim did not negate this otherwise misleading impression. Further the Panel noted that the final bullet point referred to '… a wider clinical benefit…' for Gaviscon Advance. The Panel considered that the third and fourth bullet points appeared to relate directly to the clinical situation. The data presented in support of the conclusions was from an *in-vitro* study; the Panel noted its comments above regarding the applicability of the *in-vitro* data to the clinical situation. The Panel considered the advertisement was misleading and a breach of the Code was ruled.

The advertisement entitled 'The Role for Liquid Alginate Suspension (Gaviscon Advance) in the Protection of the Oesophagus Against Damage by Pepsin in the Refluxate' referred only twice to the study at issue being *in-vitro*; the 'Methods' section described a simulated gastric refluxate and the fact that reflux events were mimicked. The 'Conclusion' section, however, did not refer to an *in-vitro* study, it appeared that all of the bullet points related directly to the clinical situation. The data presented in support of the conclusions was from an *in-vitro* study; the Panel noted its comments above regarding the applicability of the *in-vitro* data to the clinical situation. The Panel considered that the advertisement was misleading and a breach of the Code was ruled.

A public health physician complained about two advertisements (ref G-NHS-UK-51-07) for Gaviscon Advance (sodium alginate and potassium bicarbonate) issued by Reckitt Benckiser Healthcare (UK) Limited. The advertisements were titled 'The Role for Liquid Alginate Suspension (Gaviscon Advance) in the Protection of the Oesophagus Against Damage by Bile in the Refluxate' and 'The Role for Liquid Alginate Suspension (Gaviscon Advance) in the Protection of the Oesophagus Against Damage by Pepsin in the Refluxate' and were published in the BMJ of 22 March and 12 April respectively.

This case was considered under the 2008 Constitution and Procedure. Reckitt Benckiser was asked to bear in mind the requirements of Clause 7.2 which was the same in the 2008 Code as in the 2006 Code.

COMPLAINT

The complainant stated that the advertisements presented data from *in-vitro* studies but made claims about expected *in-vivo* effects. The complainant believed that the conclusions presented in both advertisements misled the reader because they made unsubstantiated claims about clinical situations that could not be reasonably extrapolated from the *in-vitro* data presented in breach of the Code.

RESPONSE

Reckitt Benckiser stated that it could see no justifiable

reason for a genuine grievance against either advertisement with respect to Clause 7.2.

The complainant suggested that *in-vivo* conclusions had been based upon the *in-vitro* studies described. In the advertisements, however, the conclusions did not make claims to suggest that either *in-vivo* studies had been conducted or that Gaviscon Advance had been proven to have *in-vivo* activity relating to bile and pepsin. All conclusions clearly related to the studies described immediately preceding and these were very obviously conducted *in-vitro* as was clearly stated on numerous occasions throughout the articles. In fact Reckitt Benckiser did not expect Gaviscon Advance to behave differently in these two instances, which was reasonable considering that Gaviscon Advance was a non-systemic product which worked by physical means but the claims made did not state an *in-vivo* action, merely that it was not unreasonable to consider this might be the case.

The advertisements concerned abstracts of two posters that had been accepted and presented at eminent scientific meetings worldwide including Digestive Disease Week, United European Gastroenterology World and the British Society of Gastroenterology Annual Meeting. The abstracts had thus been peer reviewed and were presented in full in each advertisement. No additional claims or conclusions were included with either abstract, thus those that were included were deemed accurate by experts in this field.

Furthermore the abstracts were included in the BMJ which was aimed solely at health professionals. Therefore, the target audience was scientific and the advertisements were presented in a fashion that befitted the BMJ. The abstracts were scientifically structured and included a brief background, a clear aim, sufficient details of the methods for the reader to be able to repeat the experiment if they wished, a succinct outline of the results and the authors' interpretation of the findings. It was this content that would have been considered by BMJ reviewers and then deemed to be accurate and appropriate to its readers.

PANEL RULING

The Panel noted that each advertisement was headed 'Advertisement Feature' below which appeared the relevant abstract. The Panel understood that the abstracts appeared in the advertisements essentially in the same way as they had been originally presented at the scientific meetings. Reckitt Benckiser had submitted that they were presented in full with no additional claims or conclusions. The Panel was thus concerned to note that the abstracts, although written for a scientific purpose, were now being used unchanged for a promotional purpose. The Gaviscon Advance prescribing information appeared at the bottom of the right hand page of each double page spread.

Both abstracts, and therefore both advertisements, detailed *in-vitro* studies. In that regard the Panel noted that the supplementary information to Clause 7.2 stated that care must be taken with, *inter alia*, the use of data derived from *in-vitro* studies so as to not mislead as to its significance. The extrapolation of such data to the clinical situation should only be made where there was data to show that it was of direct relevance and significance. The Panel noted that it was a principle under the Code that claims related to the clinical situation unless clearly stated otherwise.

The advertisement published on 22 March, entitled 'The Role for Liquid Alginate Suspension (Gaviscon Advance) in the Protection of the Oesophagus Against Damage by Bile in the Refluxate', featured a schematic diagram of a cell model used to assess diffusion of bile acids. Under a heading of 'Conclusion' the first bullet point clearly referred to an *in-vitro* model. The third bullet point, however, stated '*In-vivo*, the mode of action of Gaviscon Advance is expected to give oesophageal protection from the damaging potential of bile acids'. The Panel noted Reckitt Benckiser's submission that it was not unreasonable to consider that Gaviscon Advance *might* [emphasis added] produce the same results *in-vivo* as it did *in-vitro*. The company had not produced any data to support this statement. In the Panel's view, the claim was based on assumption and together with the title of the advertisement suggested that Gaviscon Advance *would* [emphasis added] protect the oesophagus from damage by bile in the refluxate; the use of the wording 'expected to give' in the claim did not negate this otherwise misleading impression. Further the Panel noted that the final bullet point referred to '… a wider clinical benefit…' for Gaviscon Advance. The Panel considered that the third and fourth bullet points appeared to relate directly to the clinical situation. The data presented in support of the conclusions was from an *in-vitro* study; the Panel noted its comments above regarding the applicability of the *in-vitro* data to the clinical situation. The Panel considered the advertisement was misleading. A breach of Clause 7.2 was ruled.

The advertisement published on 12 April, entitled 'The Role for Liquid Alginate Suspension (Gaviscon Advance) in the Protection of the Oesophagus Against Damage by Pepsin in the Refluxate', referred only twice to the study at issue being *in-vitro*; the 'Methods' section described a simulated gastric refluxate and the fact that reflux events were mimicked. The 'Conclusion' section, however, did not refer to an *in-vitro* study, it appeared that all of the bullet points related directly to the clinical situation. The data presented in support of the conclusions was from an *in-vitro* study; the Panel noted its comments above regarding the applicability of the *in-vitro* data to the clinical situation. The Panel considered that the advertisement was misleading. A breach of Clause 7.2 was ruled.

Complaint received **7 July 2008**

Case completed **26 August 2008**