PUBLIC HEALTH REGISTRAR v RECKITT BENCKISER

Promotion of Gaviscon Advance

A public health registrar alleged a breach of Clause 2 in that Reckitt Benckiser's promotion of Gaviscon Advance (sodium alginate and potassium bicarbonate) had brought discredit to, and reduced confidence in, the pharmaceutical industry because of its cumulative breaches of a similar and serious nature over the past few months.

In Case AUTH/2138/7/08 two advertisements that had appeared in the BMJ were ruled to be misleading in breach of the Code. Case AUTH/2205/2/09 referred to a third advertisement which had breached the Code.

The detailed response from Reckitt Benckiser is given below.

The Panel noted that in both Case AUTH/2138/7/08 and Case AUTH/2205/2/09 it had ruled breaches of the Code. The supplementary information to Clause 2 stated, as one example of an activity likely to be in breach of Clause 2, multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

The Panel was concerned that both the previous cases demonstrated an apparent poor knowledge of the requirements of the Code. In that regard the Panel noted that Reckitt Benckiser had initiated a compliance programme which included in-house training by an external consultant.

A ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. Despite its concerns about the previous cases the Panel did not consider that their cumulative effect was such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry as alleged. No breach of Clause 2 was ruled.

A public health registrar complained about the promotion of Gaviscon Advance (sodium alginate and potassium bicarbonate) by Reckitt Benckiser Healthcare (UK) Limited.

COMPLAINT

The complainant alleged a breach of Clause 2 of the Code by Reckitt Benckiser in its promotion of Gaviscon Advance in recent months.

In Case AUTH/2138/7/08, which referred to two advertisements for Gaviscon Advance that appeared in the BMJ last year, the Panel ruled that both advertisements were misleading in breach of the Code.

Case AUTH/2205/2/09 referred to a third advertisement for the same product, which appeared a few months later in the same journal, and had breached Clauses 6.3, 7.2, 9.10 and 12.1 of the Code. [When the Panel considered the complaint now before it, Reckitt Benckiser had accepted the Panel's rulings of breaches of the Code in Case AUTH/2205/2/09 although the complainant's appeal of a ruling of no breach of the Code had yet to be considered.]

The complainant considered that Reckitt Benckiser's activities had brought discredit to, and reduced confidence in, the pharmaceutical industry because of its cumulative breaches of a similar and serious nature in the promotion of Gaviscon Advance over the past few months.

RESPONSE

Reckitt Benckiser strongly disputed the allegation. While it had fully accepted and addressed the previous Panel rulings it did not believe the two cases were connected or could, in combination, bring discredit upon the pharmaceutical industry.

Previous cases and Panel rulings

The two cases in question were Case AUTH/2138/7/08 and Case AUTH/2205/2/09. The former was in respect of two advertisements featured in the BMJ on 22 March 2008 and 12 April 2009, the latter concerned a supplement distributed in the BMJ on 7 February 2009 that presented the findings of an advisory board meeting, this case was not yet concluded but the information presented here was based on the Panel ruling received on 18 March 2009.

Case AUTH/2138/7/08

This case concerned two advertisements reporting *in vitro* experiments that had shown Gaviscon Advance Aniseed Suspension could impede the reflux of bile and pepsin and inhibit the activity of pepsin. It was alleged that the two advertisements had presented *in vivo* conclusions based on *in vitro* experimental data. Reckitt Benckiser refuted the claim stating that the data had been presented with full experimental detail and numerous references to the fact that the studies were conducted *in vitro*. The advertisements were included in a professional journal where it was reasonable to expect the audience to understand the material presented without drawing misleading conclusions.

The Panel ruled that aspects of the material appeared to relate directly to the clinical situation and that this was misleading. A breach of Clause 7.2 was ruled in respect of each advertisement.

Case AUTH/2205/2/09

This case concerned a supplement distributed with the BMJ that reported the findings of an advisory board – a multidisciplinary group of experts brought together to discuss laryngopharyngeal reflux. The complainant questioned whether the advisory meeting had in fact taken place and was a genuine advisory board meeting. It was further alleged that the findings reported were disguised promotion. Reckitt Benckiser again disputed all the allegations and believed that the supplement, that had been reviewed and accepted by the BMJ, written by a third party and reviewed and approved by the advisory board members, was an educational supplement and not an advertisement for Gaviscon Advance.

The Panel found that Reckitt Benckiser was not sufficiently at 'arm's length' from the meeting, subsequently the supplement was ruled in breach of Clauses 6.3 and 12.1. The sponsorship declaration was not sufficient and a breach of Clause 9.1 was ruled. A breach of Clause 7.2 was also ruled as it was considered that the supplement had not fully covered all aspects noted in the introduction. No breach of Clause 9.7 was ruled as the supplement was not an extreme format or could be confused to be part of the BMJ as alleged; this was subject to an as yet unconsidered appeal by the complainant.

Action taken to ensure future compliance

Reckitt Benckiser had already taken substantial action with regard to the Case AUTH/2138/7/08 to ensure future compliance. Case AUTH/2205/2/09 was not yet concluded but steps had been taken in response to the Panel's ruling and these would be reviewed after the appeal had been heard.

Case AUTH/2138/7/08 was found in breach due to the extrapolation of *in vitro* data to suggest that Gaviscon Advance Aniseed Suspension might protect the oesophagus from the reflux of bile and pepsin in the clinical setting. Subsequently Reckitt Benckiser had amended the Gaviscon licence accordingly and updated Sections 4.1 and 5.1 of the summary of product characteristics (SPC) to include references to bile and pepsin.

As noted, Case AUTH/2205/2/09 was unresolved but Reckitt Benckiser had committed to review and improve its current processes, particularly in relation to activities with external groups. Previous cases on advisory boards and subsequent documents arising from them were under review and the company intended to consult the Authority if there was any ambiguity in its interpretation. In addition it had committed to hold regular meetings of the relevant regulatory and medical team members to examine the Code of Practice Review as a group and to record learnings from this more formally.

In the broader context of compliance, and although not specifically relevant to these cases, a wide reaching compliance programme was in progress to ensure there was a thorough knowledge of the Code and full understanding of its implementation in practice throughout the organisation. Already this year the annual NHS commercial team meeting was largely dedicated to training on the Code. The 2008 Code was presented and a full day's training was given by an external expert consultant. The company intended to repeat this process within six months with relevant marketing staff.
Reckitt Benckiser was committed to reviewing and enhancing approval and compliance procedures. Regulatory and medical staff, who were fully trained on the Code, would continue to attend repeat sessions on a regular basis, every 2-3 years to maintain an expert knowledge of the Code. To add context to the control exercised by the regulatory and medical teams, regarding production of copy, the items referred to in the complaint were two of many that were certified within the organisation. Reckitt Benckiser took the approval and certification processes very seriously and always maintained a high level of integrity when doing so. In the last twelve months nearly 600 pieces had been certified, of which around 100 had been subject to the Code. Reckitt Benckiser was predominantly an over-the-counter company and as such the remainder of items were more commonly subject to the Proprietary Association of Great Britain Code.

The implications of the breaches ruled

Both cases at issue had highlighted areas in which the Reckitt Benckiser should, and had, taken action to ensure Code compliance was maintained. Any breach of the Code was significant and the company took complaints very seriously. The complainant noted that it was the serious nature of both breaches that should result in a subsequent breach of Clause 2. There were degrees of severity depending on the implications of different breaches, which was further borne out by reviewing previous cases ruled in breach of Clause 2. Reckitt Benckiser considered that the breaches ruled in the two cases at issue were not of such severity that any discredit had been brought upon the pharmaceutical industry or that confidence in the industry had been undermined, particularly in light of the rulings of the previous case.

In Case AUTH/2138/7/08 the breach resulted from issues relating to the extrapolation of data; in Case AUTH/2205/2/09 the breaches related to the means in which information was communicated. In neither case was the accuracy of the data or information at fault. Consequently these breaches had not resulted in inappropriate prescribing or use of Gaviscon Advance, either in isolation or in preference to a

more suitable product. More importantly there was never even minimal risk to patient safety. In Case AUTH/2138/7/08 claims about protection of the oesophagus from the reflux of bile and pepsin were found to be misleading. The product licence for Gaviscon Advance Aniseed Suspension had subsequently been updated and similar claims could be fully substantiated. In Case AUTH/2205/2/09 the report of the advisory board, comprising expert health professionals was approved by the advisory board members prior to publication. This focussed on laryngopharyngeal reflux and currently Gaviscon Advance Aniseed Suspension was the only product licensed for the symptomatic relief of this condition. Notably in neither case was the information made available to patients or the public, it was only available to health professionals via a distinguished medical journal that had approved the material.

Furthermore, the complainant suggested that these were cumulative breaches of a similar and serious nature. Indeed, if Case AUTH/2205/2/09 was to represent a breach of undertaking of Case AUTH/2138/7/08 this would be a reasonable assertion and would demonstrate disregard for previous rulings and a serious failing that might bring the industry into disrepute. This was not the case however and the two cases were quite unrelated and occurred almost a year apart.

Reckitt Benckiser accepted that in both cases a breach of Clause 7.2 was ruled, however in Case AUTH/2138/7/08 this related to a claim that was deemed unsubstantiated by the data, due to its extrapolation to the clinical situation. In Case AUTH/2205/2/09 no similar or related material had been used, the topic of the piece was completely different and the breach was not related to any claims. The medical writer had suggested in the introduction to the supplement that management of gastro-oesophageal reflux disease would be discussed alongside a number of other topics but this was not accurate as the focus of the piece was laryngopharyngeal reflux.

To state, therefore, that these breaches were of a cumulative, similar and serious nature misrepresented the cases and the previous findings of the Panel. Reckitt Benckiser stressed that these breaches were not acceptable and would not be repeated, but it would further assert that they were not of a similar nature that would suggest a disregard for previous rulings. They did not therefore bring discredit upon or reduce confidence in the industry.

The previous cases ruled in breach of Clause 2

The breaches of Clause 2 ruled in the last two years generally fell into a number of categories where:

- action resulting in a breach of the Code directly impacted patients or the public
- action resulting in a breach of the Code directly impacted prescribing habits
- there had been a breach of previous undertaking
- promotion of medicines had occurred without a marketing authorization.

Impact on patients might have occurred either by direct promotion to the patients or the public, by offering patients incentives to request a particular medicine or even risking their safety. Direct impact on the prescribing of a medicine might have resulted in its inappropriate use, either by misrepresentation of a medicine, or its features comparative to other therapies or by attempting to offer incentives to health professionals to prescribe a certain product. A breach of previous undertaking was deemed to show serious disregard for authority rulings; be that the Authority or the Medicines and Healthcare products Regulatory Agency. Promotion without a marketing authorization had occurred due to activity prior to the grant of a licence.

There were undoubtedly serious consequences that might be expected to bring discredit upon the pharmaceutical industry and in all these previous cases the impact of the activity found to be in breach far outweighed any implications of the breaches ruled in Case AUTH/2138/7/08 and AUTH/2205/2/09.

It was feasible that a pharmaceutical company could misinterpret the Code without bringing the industry into disrepute or undermining confidence, which would imply serious misconduct or deliberate deception. Occasional breaches were not uncommon; many companies were subject to multiple breaches without ever bringing the industry into disrepute and thus being ruled in breach of Clause 2. While it was not acceptable to be found in breach of the Code, Reckitt Benckiser considered that the breaches described in Cases AUTH/2138/7/08 and AUTH/2205/2/09 were not of such serious or similar nature that they could, even in combination, constitute a breach of Clause 2. Furthermore, it was noted in the supplementary information to Clause 2 that 'A ruling of a breach of this clause is a sign of particular censure and is reserved for such circumstances'.

Examples of activities that were likely to be in breach of Clause 2 included prejudicing patient safety and/or public health, excessive hospitality, inducements to prescribe, inadequate action leading to a breach of undertaking, promotion prior to the grant of a marketing authorization, conduct of company employees/agents that fell short of competent care and multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

Neither the material at issue nor any of the breaches ruled in Cases AUTH/2138/7/08 and AUTH/2205/2/09 could fall within any of the examples given above.

In conclusion, the cases cited in the complaint had been reviewed and significant action had, and was, being taken to ensure no breach of undertaking was

possible. Steps were being taken to tighten control and improve compliance with the Code; this was and would continue to be taken very seriously at Reckitt Benckiser. It was committed to abiding by the Code now and in the future.

PANEL RULING

The Panel noted that in Case AUTH/2138/7/08 it had ruled breaches of the Code because data presented in support of clinical conclusions was from *in-vitro* studies. Furthermore, in its consideration of the case the Panel had noted that the two advertisements at issue were essentially scientific abstracts as originally presented at scientific meetings. The Panel had noted its concerns that the abstracts, although written for a scientific purpose, had been used unchanged for a promotional purpose.

In Case AUTH/2205/2/09, the proceedings of a Reckitt Benckiser advisory board had been presented as an apparently independent educational supplement in the BMJ. The Panel had considered *inter alia*, that the material was a disguised advertisement for Gaviscon Advance.

The Panel noted that the supplementary information to Clause 2 stated, as one example of an activity likely to be in breach of Clause 2, multiple/cumulative breaches of a similar and serious nature in the same therapeutic area within a short period of time.

The Panel was concerned that both the previous cases demonstrated an apparent poor knowledge of the requirements of the Code. In that regard the Panel noted that Reckitt Benckiser had initiated a compliance programme which included in-house training by an external consultant.

A ruling of a breach of Clause 2 was a sign of particular censure and reserved for such. Despite its concerns about the previous cases the Panel did not consider that their cumulative effect was such as to bring discredit upon, or reduce confidence in, the pharmaceutical industry as alleged. No breach of Clause 2 was ruled.

Complaint received **20 March 2009**

Case completed **12 May 2009**