CASE AUTH/2114/4/08

PRACTICE PHARMACIST v RECKITT BENCKISER HEALTHCARE

Gaviscon Advance journal advertisement

The practice pharmacist at a medical centre complained about the strapline 'Reflux super-suppressant' in an advertisement for Gaviscon Advance (sodium alginate/potassium bicarbonate), issued by Reckitt Benckiser Healthcare, which had appeared in the BMJ. The complainant considered that 'super' implied either a comparison to other reflux suppressants, yet this was not justified or referenced in the advertisement, or that the product was of a higher quality than alternative, again this was not qualified or referenced.

The Panel considered that describing Gaviscon Advance as a super-suppressant implied that it had qualities/properties well beyond those associated with other reflux suppressants. This was a very strong and broad claim for general superiority. The question was, could such a claim be substantiated?

The advertisement referred to the use of Gaviscon Advance in hoarseness, cough and sore throat associated with laryngopharyngeal reflux. In that regard the Panel noted that Gaviscon Advance was the only reflux suppressant to be so licensed. Further, data submitted by Reckitt Benckiser showed that in terms of raft strength and resilience and duration of action Gaviscon Advance was better than other products tested. The Panel noted, however, that not all the available reflux suppressants had been examined. The Panel also noted, *inter alia*, some of the features of Gaviscon Advance which Reckitt Benckiser submitted were unique were only unique inasmuch as relevant data had not been generated for the other products. For instance, although the company stated that Gaviscon Advance did not affect the bioavailability of proton pump inhibitors, no data was provided to show the converse for all other alginates – it appeared that Gaviscon Advance was the only product for which there was relevant data.

On balance the Panel considered that the strapline 'reflux super-suppressant' was a claim for general superiority which could not be substantiated. The Panel also considered that the claim was misleading. Breaches of the Code were ruled.

Although noting its rulings above, the Panel did not consider that high standards had not been maintained.

The practice pharmacist at a medical centre complained about an advertorial for Gaviscon Advance (sodium alginate/ potassium bicarbonate) issued by Reckitt Benckiser Healthcare (UK) Limited, which had appeared In the BMJ on 5 April. Below the depiction of a bottle of Gaviscon Advance was the strapline 'Reflux super-suppresant'.

COMPLAINT

The complainant considered that 'super' implied one of two things. Either there was a comparison to other reflux suppressants, yet this was not justified or referenced elsewhere in the advertisement, or the product was of a higher quality than alternative, again this was not qualified or referenced.

The complainant alleged breaches of Clauses 7 and 9 of the Code.

When writing to Reckitt Benckiser to inform it of the complaint, the Authority asked it to consider the requirements of Clauses 7.2, 7.4, 7.10 and 9.1.

RESPONSE

Reckitt Benckiser considered that both of the complainant's concerns related to 'super-suppressant' being a comparative claim. Reckitt Benckiser disagreed; the term 'super' was not itself a comparative claim, in this context it was merely a statement about the efficacy of the product in the same way that numerous products claimed 'great' and 'excellent' efficacy. This was supported by the new licensed indication covering 'symptoms of laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throats and cough' which complemented the existing indication for 'gastro-oesophageal reflux'. In addition, the licence now also covered use along with acid suppression therapy. All of these licence extensions were clearly stated on the advertisement. As such Gaviscon Advance presented a comprehensive or 'super' treatment for the symptoms of reflux. Hence, the use of term 'super' in this advertisement was a statement about the product's comprehensive efficacy and not a comparative claim.

Despite the above, even if 'super-suppressant' was considered a comparative claim, the licensed particulars, the method of action and the clinical and *in vitro* data for Gaviscon Advance would still support and justify it. The term 'super' did not mean the best, it was not an exaggeration, nor an all embracing claim, it simply meant very good. Gaviscon Advance could justify 'super' and 'very good' since it had the most comprehensive indications for the treatment of the symptoms of reflux, with the 'treatment of the symptoms of

laryngopharyngeal reflux such as hoarseness and other voice disorders, sore throats and cough' being unique to the product. 'Super' was also supported by both clinical and *in vitro* data where Gaviscon Advance had demonstrated superior properties to other available reflux suppressants.

Reckitt Benckiser explained that Gaviscon Advance was a 'second generation' alginate reflux suppressant indicated for the symptomatic relief of gastro-oesophageal reflux. Gaviscon Advance contained the active ingredients, per 10ml dose, sodium alginate (1000mg) and potassium bicarbonate (200mg), which was double the concentration of sodium alginate compared with other available alginates such as Liquid Gaviscon.

Gaviscon Advance did not work via systemic absorption; it had a physical mode of action, whereby on contact with the gastric contents sodium alginate reacted to form an alginic acid gel. The gel then entrapped carbon dioxide, produced by reaction of potassium bicarbonate with acid in the stomach, forming a buoyant aerated raft that floated on top of the stomach contents and prevented gastric reflux into the oesophagus. The raft might also be refluxed preferentially into the oesophagus where, by virtue of its neutral pH, it protected the oesophageal mucosa from corrosive attack. Gaviscon Advance also contained calcium carbonate as an excipient which provided calcium ions that strengthened the alginate raft by cross-linking within it.

Gaviscon Advance was proven to form a stronger and more resilient raft than other alginates and that it was effective in suppressing acid reflux to relieve the symptoms of gastro-oesophageal reflux. Gaviscon Advance was also proven to reside in the stomach for longer than some other alginates; 4 hours compared with 2 hours for Peptac and Acidex. The unique qualities of Gaviscon Advance included the indications for symptomatic relief of laryngopharyngeal reflux and the concomitant prescribing with proton pump inhibitors, Gaviscon Advance was also the only alginate proven to protect the oesophagus from damage by bile and pepsin.

Reckitt Benckiser therefore believed that there were no breaches of Clauses 7.2, 7.4 or 7.10, since there was no unfair comparison, the claim was fair, balanced and capable of substantiation, there was no undue exaggeration, and there was no information that would have a negative effect on rational prescribing. As such there had also not been any breach of Clause 9.1, since high standards had been maintained and this was further confirmed by the fact that this was an isolated complaint, and that other professionals viewing this advertisement had understood the meaning and intent of the claim.

PANEL RULING

The Panel considered that describing Gaviscon Advance as a super-suppressant implied that it had qualities/properties well beyond those associated with other reflux suppressants. This was a very strong and broad claim for general superiority. The question was, could such a claim be substantiated?

The advertisement in question referred to the use of Gaviscon Advance in hoarseness, cough and sore throat associated with laryngopharyngeal reflux. In that regard the Panel noted that Gaviscon Advance was the only reflux suppressant to be so licensed. Further, data submitted by Reckitt Benckiser showed that in terms of raft strength and resilience, Gaviscon Advance was better than other products tested. The Panel noted, however, that not all the available reflux suppressants had been examined. Similarly, although the duration of action of Gaviscon Advance was longer than other products it had only been compared with four other agents. The Panel also noted Reckitt Benckiser's submission that Gaviscon Advance was the only alginate indicated for treatment of the symptoms of gastro-oesophageal reflux during concomitant treatment with or following withdrawal of acid suppressing therapy. There was no specific mention in the summary of product characteristics (SPC) of proton pump inhibitors in this regard. Some of the features of Gaviscon Advance which Reckitt Benckiser submitted were unique were only unique inasmuch as relevant data had not been generated for the other products. For instance, although the company stated that Gaviscon Advance did not affect the bioavailability of proton pump inhibitors, no data was provided to show the converse for all other alginates – it appeared that Gaviscon Advance was the only product for which there was relevant data.

On balance the Panel considered that the strapline 'reflux super-suppressant' was a claim for general superiority which could not be substantiated. Breaches of Clauses 7.10 and 7.4 were ruled. The Panel also considered that the claim was misleading. A breach of Clause 7.2 was ruled.

Although noting its rulings above, the Panel did not consider that high standards had not been maintained. No breach of Clause 9.1 was ruled.

Complaint received **7 April 2008**

Case completed **28 May 2008**