ANONYMOUS REPRESENTATIVE v ALCON

Promotion of Azarga

An anonymous Alcon representative complained about the company's alleged unethical promotion of Azarga (brinzolamide/timolol) eye drops for glaucoma. The complainant explained that representatives had been given litmus paper and bottles of Azarga and Cosopt (a competitor product) in order to practically demonstrate the pH differences between the two. The complainant alleged that representatives had been encouraged to instil the eye drops into their own eyes and those of their customers; one doctor had reportedly suffered an adverse event. The complainant stated that representatives were asked by their managers to 'dampen down' on the practice as the competition was upset but submitted that the sensationalism had worked too well for any of his team to stop.

The detailed response from Alcon is given below.

The Panel noted that a complainant had the burden of proving their complaint on the balance of probabilities. Anonymous complaints, like all complaints were judged on the evidence provided by both parties. In this case, the complainant had provided no evidence to support their allegations and as they had also not provided any contact details there was no way to ask them to provide further and better particulars.

The Panel noted that one page of the Azarga detail aid highlighted the difference in pH between Azarga and Cosopt. One of the slides from the representatives' briefing showed bottles of both eye drops and some litmus paper. In the Panel's view it was not unreasonable for representatives to practically demonstrate the pH difference between the two products. It was not unacceptable under the Code for representatives to hold supplies of medicines and Alcon's record of the quantity and destination of all of the eye drops supplied to the field force did not seem incompatible with their use to demonstrate pH differences.

The Panel noted that representatives had been asked to demonstrate the pH differences between Azarga and Cosopt in February 2010, a year before the complaint was received; despite the passage of time the complainant had provided no evidence to show that representatives had been encouraged to instil the eye drops either into their own eyes or those of their customers. Neither had any evidence been provided to show that managers had instructed the representatives to 'dampen down' the practice. The Panel noted Alcon's submission that it was not unusual for an ophthalmologist to unilaterally decide to try eye drops out on themselves so that they knew if, and how much, discomfort each produced on instillation. In the Panel's view it was not unreasonable that the ophthalmologists might report the results back to the representatives.

The Panel noted that the representatives had not been trained on how to instil eye drops. It would have been helpful, given ophthalmologists' propensity to try out eye drops, to have reminded representatives not to let them use the demonstration bottles. However, there was no evidence that representatives had been briefed to instil the eye drops either into their own eyes or those of their customers as alleged and no evidence that representatives had proactively encouraged ophthalmologists to instil the demonstration eye drops. No breach of the Code was ruled.

The eye drops had not been provided as samples and so there could thus be no breach of the Code in that regard.

The Panel noted its rulings above and considered that there was no evidence to show that high standards had not been maintained. No breach of the Code was ruled including no breach of Clause 2.

An anonymous, non-contactable representative of Alcon Laboratories (UK) Limited, complained about the company's alleged unethical promotion of Azarga (brinzolamide/timolol), an eye drop preparation for the treatment of glaucoma.

COMPLAINT

The complainant submitted that in late 2010 representatives were given litmus paper and samples of Azarga and a competitor product, Cosopt, to use in sales calls to highlight 'huge' pH differences between the two products. A number of colleagues had been very concerned that representatives had the medicines at all but even more alarming was that many had been 'encouraged' to instil the eye drops either into their own eyes or into the eyes of their customers. The complainant stated that he had been horrified to hear that lots of doctors actually tried a drop in each eye first of all but the fact that the representatives were not health professionals but had administered prescription only medicines and that one doctor had an adverse event as he was beta blocker intolerant (the incident was not reported as the doctor was a friend of the representative), was frankly disgusting!

The complainant stated that representatives were asked by their managers to dampen down on the practice just before Christmas as the competition was upset but submitted that the sensationalism had worked too well for any of his team to stop!

In the complainant's view, the competition in this case was too weak to complain as Alcon had beaten it on a number of occasions already but the complainant was very worried about a complaint about him personally so wanted to bring some of the unethical behaviour he was being pushed to do to the Authority's attention.

When writing to Alcon, the Authority asked it to respond in relation to Clauses 2, 9.1, 15.2, 15.9 and 17 of the 2008 Code.

RESPONSE

Alcon stated that the complaint appeared to relate to a product demonstration that was introduced to its medical sales representatives in February 2010. This demonstration was intended to assist in the promotion of Azarga, which was a fixed-dose combination, topical anti-glaucoma therapy containing the beta-blocker, timolol, and the carbonic anhydrase inhibitor, brinzolamide. There was only one other similar combination product on the market, Cosopt, marketed by Merck Sharp & Dohme, which also contained timolol but in combination with dorzolamide. Both products were designed to reduce raised intraocular pressure in patients suffering from glaucoma or ocular hypertension. Since Cosopt was the first product of this type to be introduced in the UK, it currently had a greater market share. It was therefore understandable that the main focus of Alcon's promotional efforts for Azarga was a comparison of the product with Cosopt.

Clinical studies had demonstrated no statistically significant difference in efficacy between Azarga and Cosopt. However, Cosopt produced statistically significantly more stinging and discomfort upon instillation than Azarga. This difference was attributed to a difference in the pH of the two products. Tears had a pH that was close to neutral (pH 7) and it was generally considered that, for maximum comfort upon instillation, an eye drop should also have a pH that was as close to neutral as possible. Azarga had a pH of 7.2, while Cosopt had the much more acidic pH of 5.6. This difference between the products had been emphasised in Alcon's promotional material, where it had been illustrated by the colour difference obtained when the two products were applied to a pH indicator strip. It was suggested during a sales cycle meeting that this message could be reinforced during a sales representative's detail by a practical demonstration in which a drop of each product was applied to pH indicator paper in front of the doctor. The colours produced could then be related to the visual in Alcon's promotional material to support the claim made.

For this reason, all representatives (approximately 30) were give 1 or 2 bottles of Azarga and Cosopt (consistent with the purpose intended), and strips of pH indicator paper. The quantity, details and destination of all product supplied for this purpose were recorded and after this initial, very limited supply, further supplies of product had to be requested by a representative in writing and these supplies were also recorded, so that it could be confirmed, based on the call pattern of the representative, that product was only being used as intended. Alcon's records showed that 77 bottles of Cosopt had been provided to representatives since the initiative was started, the last of which was provided in December 2010.

Alcon noted that the eye drops supplied should not be considered as 'samples' as defined in Clause 17, since they were not intended to be handed over or delivered to a health professional and were for the use of the representative only in the manner described. The strict control and documentation of the quantity supplied ensured that eye drops were only being used as intended and it was clear from Alcon's records that no product could have been left with health professionals as 'samples'.

The briefing material used for this programme was page 6 of the Azarga detail aid used in February 2010. A copy of detail aid was provided for information (it was superseded in May 2010). In addition, a slide conveying the essence of the demonstration, containing images of the two eye drops and the pH indicator paper to be used, was displayed during the briefing at a sales cycle meeting held in January 2010 and a copy of this presentation was provided. The slide contained a build so that the product images were displayed initially, followed by the pH values and finally the image of the pH indicator paper. No further briefing material was considered to be necessary, since the demonstration was such a simple procedure and a practical demonstration was also given at the time.

The product demonstration programme that was instituted to support the promotion of Azarga, that Alcon believed formed the basis of this complaint, was outlined above. Alcon could not comment further on the allegations since they appeared to be unsubstantiated and disingenuous and were not consistent with the briefing given to Alcon's representatives. In Alcon's view, if the complainant's grievances were genuine, then the representative or representatives in question would have at least broached the matter with line management or with Alcon's human resources department (which would deal confidentially with such matters). No such representation had been made. In any event, the idea that an ophthalmologist would allow a representative to instil an eye drop into their eyes, which seemed to be the implication in the complaint, was beyond comprehension. It might be that a misunderstanding arose on the part of the complainant because some ophthalmologists decided unilaterally to try the two products in their own eyes; indeed Alcon was aware that this happened on a handful of occasions. However, this was not the objective of the demonstration and Alcon could not be responsible for actions taken by the ophthalmologists on their own initiative. Alcon was not aware that any of its representatives tried the drops in their own eyes as suggested, and in any event no evidence had been provided for this

allegation. In addition, the assertion that Alcon's competitor was 'too weak' to protect its own interests was also not consistent with Alcon's experience, nor, it believed, with that of the PMCPA and, in Alcon's opinion, raised further doubt about the validity of the complaint. Alcon had, however, instructed representatives to cease this activity pending the Panel's ruling.

In response to a request for further information, Alcon submitted that, as described above, its representatives had been instructed to demonstrate the pH difference between Azarga and Cosopt. This demonstration formed part of Alcon's promotional strategy, which concentrated on highlighting comfort differences between Azarga and the current market leader, an attribute which Alcon considered would have a positive influence on patient compliance. Alcon noted that it had stated that it knew, through its representatives, that some ophthalmologists had decided unilaterally to try Azarga and Cosopt in their own eyes. Alcon stated that it could not provide more details and noted that it was not unusual for an ophthalmologist to instil an eye drop into their own eye(s), to enable them to appreciate drop comfort. Compliance with therapy was extremely important for glaucoma patients and could be influenced by any significant discomfort produced when an eye drop was instilled. Glaucoma specialists therefore occasionally liked to make a personal comparison of the type described to assist in differentiating between treatments that appeared to have similar efficacy.

In view of the above, Alcon would not necessarily record every occasion upon which an ophthalmologist told the company that they had tried one of its products or a competitor product personally and so could not confirm accurately how common this practice was, or provide details on the source of product used on each occasion. Alcon, however, confirmed that it had no record that any of its representatives had instilled any eye drop into customers' eyes as alleged. The company also confirmed that its representatives were not given any practical training concerning instillation of eye drops, since it was not considered that that was relevant to the performance of their duties.

In addition, Alcon did not consider that there was any reason why an ophthalmologist should not try products in this way, if they chose to do so, and did not believe that it was the company's responsibility to pass any comment on the practice.

PANEL RULING

The Panel noted that the Constitution and Procedure clearly stated that a complainant had the burden of proving their complaint on the balance of probabilities. Anonymous complaints, like all complaints were judged on the evidence provided by both parties. The Panel noted that in this case, the complainant had provided no evidence to support their allegations and as they had also not provided any contact details there was no way to ask them to provide further and better particulars.

The Panel noted that one page of the Azarga detail aid highlighted the difference in pH between Azarga and Cosopt. One of the slides from the representatives' briefing showed bottles of both eye drops and some litmus paper. In the Panel's view it was not unreasonable for representatives to practically demonstrate the pH difference between the two products. It was not unacceptable under the Code for representatives to hold supplies of medicines and the Panel noted Alcon's submission that it had recorded the quantity, details and destination of all of the eye drops supplied to the field force. The product demonstration was introduced to the 30 or so representatives in February 2010 and by December of that year 77 bottles of Cosopt had been supplied. In the Panel's view this quantity did not seem incompatible with their use to demonstrate pH differences.

The Panel noted that representatives had been asked to demonstrate the pH differences between Azarga and Cosopt in February 2010, a year before the complaint was received; despite the passage of time the complainant had provided no evidence to show that representatives had been encouraged to instil the eye drops either into their own eyes or those of their customers. Neither had any evidence been provided to show that managers had instructed the representatives to 'dampen down' the practice. The Panel noted Alcon's submission that it was not unusual for an ophthalmologist to unilaterally decide to try eye drops out on themselves so that they knew if, and how much, discomfort each produced on instillation. In the Panel's view it was not unreasonable that the ophthalmologists might report the results back to the representatives.

The Panel noted that the representatives had not been trained on how to instil eye drops. It would have been helpful, given ophthalmologists' propensity to try out eye drops, to have reminded representatives not to let them use the demonstration bottles. However, there was no evidence that representatives had been briefed to instil the eye drops either into their own eyes or those of their customers as alleged; no breach of Clause 15.9 was ruled. There was no evidence that representatives had proactively encouraged ophthalmologists to instil the demonstration eye drops. No breach of Clause 15.2 was ruled.

The Panel noted that the eye drops provided to the representatives had not been provided as samples to be given to a health professional so that they might familiarize themselves with them and acquire experience in dealing with them. There could thus be no breach of Clause 17.

The Panel noted its rulings above and considered that there was no evidence to show that high standards had not been maintained. No breach of Clause 9.1 was ruled. It thus followed that there could be no breach of Clause 2.

Complaint received **21 February 2011**

Case completed **27 April 2011**