

ANONYMOUS MEMBER OF THE PUBLIC v SANOFI-AVENTIS

Statements to the public about Lantus

The anonymous mother of a diabetic child alleged that an athlete had promoted Lantus (insulin glargine) to members of the public during a local hospital fun day which she and her son, a type 1 diabetic, had attended. The matter was taken up with Sanofi-Aventis.

The complainant explained that while the children were playing, she was invited, with the other parents, to a presentation on sports and insulin, which interested her a lot, as her son was a keen footballer. One of the speakers gave a very impressive presentation on his sporting successes. The complainant was very interested in how well he managed to control his sugars. He kept referring to an insulin called Lantus and how good it was. The complainant also looked at his website and was very impressed.

The complainant stated that she naturally thought her son would benefit from Lantus, as he sometimes found it difficult to get the balance of sugars right, especially during the start of training for the football season. The complainant spoke to her son's consultant who seemed a bit annoyed (sometimes he was very busy) and stated that it had taken him years to get him stable on his current insulins, and that patients should not be talking about their treatments like this.

The complainant then spoke with her GP who suggested she contact the Authority because she had found out from one of the other parents afterwards that the speaker was sponsored by a pharmaceutical company.

The Panel noted that the speaker was a known Lantus user and that Sanofi-Aventis, *inter alia*, facilitated his appearance at patient group meetings to talk about his personal experience of diabetes and consequently his treatment. As explained by Sanofi-Aventis it would be impossible for him to talk only about his diabetes without mentioning his treatment.

The Panel noted Sanofi-Aventis' submission that the speaker's story inspired those who heard it. The Panel acknowledged that the speaker was expressing his own opinion about his treatment with Lantus but considered that those opinions would have been well known to Sanofi-Aventis which knew that he used Lantus and was very positive about its benefits. The section of the speaker's website which detailed diabetes management referred specifically to Lantus and stated, *inter alia*, 'Lantus allows me more flexibility so I race better, eat better and in general feel better so when I walk up to the start line I know

I can race 100% just like everyone else'.

The Panel considered that, given the arrangements that existed between them, Sanofi-Aventis was responsible under the Code for statements made by the speaker at the meeting in question. If it were otherwise then the effect would be for companies' support of patients known to be positive about their products to be used as a means of avoiding the restrictions in the Code.

The Panel noted that it had not been provided with either a copy of the presentation or a transcript of what had been said at the fun day meeting although from the complaint it was clear that the speaker had commented positively about Lantus. The Panel considered that the balance of probability was, that during his talk, statements were made by the speaker which encouraged members of the public to ask their doctor to prescribe Lantus; the complainant had certainly been encouraged to do so. A breach of the Code was ruled. The Panel considered that the overall arrangements were such that Sanofi-Aventis had not upheld high standards and a further breach of the Code was ruled.

The Panel was concerned about the arrangements, noting in particular the effect of the presentation on the complainant and the Panel's ruling in this regard. However, in the absence of a more detailed account of precisely what was said it was not possible to determine whether on the balance of probabilities the presentation was, in effect, an advertisement for Lantus to the general public and thus no breach of the Code was ruled in that regard.

The anonymous mother of a diabetic child alleged that an athlete had promoted Lantus (insulin glargine) to members of the public during a local hospital fun day. The matter was taken up with Sanofi-Aventis.

COMPLAINT

The complainant explained that she had a type 1 diabetic son and had attended a hospital fun day. While the children were playing, the complainant was invited, with the other parents, to attend a presentation on sports and insulin, which interested her a lot, as her son was a keen footballer.

One of the speakers, gave a very impressive presentation on his sporting successes. The complainant was very interested in how well he managed to control his sugars. He kept referring to an insulin called Lantus and how good it was. The

complainant also looked at his website and was very impressed.

The complainant stated that she naturally thought her son would benefit from using Lantus too, as he sometimes found it difficult to get the balance of high and low sugars right, especially during the start of training for the football season, when he had a couple of bad hypos last year.

The complainant brought this up with his consultant who seemed a bit annoyed (sometimes he was very busy) and stated that it had taken him years to get him stable on his current insulins, and that patients shouldn't be talking about their treatments like this.

The complainant then spoke with her GP who suggested she contact the Authority because she had found out from one of the other parents afterwards that the speaker was sponsored by a pharmaceutical company.

When writing to Sanofi-Aventis the Authority asked it to respond in relation to Clauses 2, 9.1, 20.1 and 20.2 of the Code.

RESPONSE

Sanofi-Aventis explained that the speaker first became known to the company in 2005 when he sought support to compete in the world championships. This arose after he came to know a company employee through his athletic club, and as a person with diabetes made a request through them for sponsorship. A sum of £1,000 was freely given to support his world championship involvement.

The speaker's next involvement with the company was in the form of an appearance at a sales conference, where he gave his perspective of living with diabetes. This was in response to a desire to share an inspirational experience of how successful control of a person's diabetes could affect their success in life. He gave both a moving and impactful description of his successes and how he had managed to progress his sporting achievements to a world stage through optimal self-management of his condition. This talk included all aspects of his therapy, including products manufactured by both Sanofi-Aventis and other companies. For this talk he was paid for the time spent away from work and home; travel/accommodation was arranged by Sanofi-Aventis.

This presentation was so inspiring that it was agreed that his experiences would be valuable to share with health professionals to show that diabetes was far from a limiting disease, but could be compatible with a normal life (or that of an elite athlete). Sanofi-Aventis therefore subsequently commissioned him to speak to small meetings restricted to health professionals on his experience of succeeding with diabetes. From the outset he was briefed on the requirement to present on his own experiences as a patient and not to consider that he was there representing Sanofi-Aventis. He produced his own presentation which was focused on

his own experience of diabetes and how his self management strategy impacted his performance, without any company involvement. The presentation referred to the various products used to manage his condition, appropriate to the audience. As would be expected, he was compensated financially for his time whenever he spoke at a Sanofi-Aventis sponsored meeting, (details were provided). Travel and any accommodation expenses had always been repaid at cost.

As regards speaking to patient groups, Sanofi-Aventis knew of a handful of occasions when this had been facilitated by the company, in that he had been proposed as a speaker if asked by meeting organisers for a recommendation. Having made such a recommendation, Sanofi-Aventis then had no further input on the title or content of the presentation, nor had it provided any support or materials in preparation of the presentations. These arrangements included the meeting in question. As regards company attendance at these meetings, a Sanofi-Aventis representative only attended if specifically requested to do so by the organiser, but never to promote specific medicines.

Sanofi-Aventis submitted that it had had no involvement in the choice of topics nor the contents of presentations made at any of these meetings, and nor had it provided any content for inclusion in presentations. In view of this, Sanofi-Aventis did not consider that it had made any attempt to promote medicines either directly or indirectly to the public, and that no breach of Clause 20.1 had occurred. Similarly, as he spoke entirely on his own account without any input or influence from Sanofi-Aventis, the company did not consider it was accountable for any content or answers to questions that he gave and that no breach of Clause 20.2 had occurred.

In terms of support for speaking to patient groups, Sanofi-Aventis paid for time and travel in accordance with the policy outlined above. The company considered that it would be unfair not to do so having recommended him as a speaker in the first instance, and the meetings were usually organised with little or no budget available to the organisers and would not go ahead without this support. A payment was made to support his attendance at the meeting in question.

Finally, there was no doubt that the speaker was an inspiration through his achievements within sport whilst successfully managing his diabetes. Although he had been briefed not to promote individual insulins to the public, he discussed his own treatment (Lantus and other non Sanofi-Aventis products) during presentations to patient groups. He considered that to try and gloss over this would be disingenuous as most patients were very knowledgeable about their own treatments. If he omitted this detail, he was invariably asked the question directly and had to answer regardless. The only way to avoid these discussions would be to stop him making any presentation to the public at all. The impact would be to deprive patients and health professionals of the opportunity to see how elite performance could be combined with diabetes.

This story inspired those who heard it, and rather than reducing confidence in the industry, Sanofi-Aventis was proud to have facilitated the sharing of such a story. This activity had helped many patients improve their own self-esteem and had made a positive difference to their lives, and rather than breaching Clauses 9.1 and 2, facilitating such an encounter was an example of something positive that the industry offered to healthcare. It was with some regret, therefore, that the company had suspended any involvement with him pending the outcome of this case, but hoped that a resolution satisfactory to all could be achieved.

Sanofi-Aventis stated that the complaint had served as a prompt to re-brief him on its requirements as a company, and how he could help these by continuing to focus his presentation on his condition rather than its treatment. In addition, all employees had been re-briefed on the company's rigorous requirements regarding the arrangements for promotional meetings. Sanofi-Aventis, considered, however, that these procedures remained consistent with the requirements of the Code and the maintenance of high standards.

PANEL RULING

The Panel noted that the speaker was a known Lantus user and that Sanofi-Aventis, *inter alia*, facilitated his appearance at patient group meetings to talk about his personal experience of diabetes and consequently his treatment. As explained by Sanofi-Aventis it would be impossible for him to talk only about his diabetes without mentioning his treatment.

The Panel noted Sanofi-Aventis' submission that the speaker's story inspired those who heard it. The Panel acknowledged that he was expressing his own opinion about his treatment with Lantus but considered that those opinions would have been well known to Sanofi-Aventis; the company knew that he used Lantus and was very positive about its benefits. The section of his website which detailed diabetes management referred specifically to Lantus and stated, *inter alia*, 'Lantus allows me more flexibility so I race better, eat better

and in general feel better so when I walk up to the start line I know I can race 100% just like everyone else'.

The Panel considered that, given the arrangements that existed between them, Sanofi-Aventis was responsible under the Code for statements made by the speaker at the meeting in question. If it were otherwise then the effect would be for companies' support of patients known to be positive about their products to be used as a means of avoiding the restrictions in the Code.

The Panel noted that it had not been provided with either a copy of the presentation or a transcript of what was said at the fun day meeting although from the complaint it was clear that the speaker had commented positively about Lantus. The Panel considered that the balance of probability was that during his talk, statements were made by the speaker which encouraged members of the public to ask their doctor to prescribe Lantus; the complainant had certainly been encouraged to do so. A breach of Clause 20.2 was ruled. The Panel considered that the overall arrangements were such that Sanofi-Aventis had not upheld high standards. A breach of Clause 9.1 was ruled.

The Panel was concerned about the arrangements, noting in particular the effect of the presentation on the complainant and the Panel's ruling in this regard. However, in the absence of a more detailed account of precisely what was said it was not possible to determine whether on the balance of probabilities the presentation was, in effect, an advertisement for Lantus to the general public and thus no breach of Clause 20.1 was ruled.

The Panel did not consider that the circumstances were such as to justify a ruling of a breach of Clause 2 which was used as a sign of particular censure and reserved for such use.

Complaint received	8 February 2007
Case completed	11 April 2007