CASE AUTH/2332/7/10

ANONYMOUS v GRÜNENTHAL

Versatis poster presentation

An anonymous and non-contactable complainant complained about a poster entitled 'Localised Neuropathic Pain' which referred to the use of Versatis (lidocaine plaster), a product supplied by Grünenthal. At the base of the poster in small type was 'Sponsored by an unrestricted educational grant by Grünenthal UK Ltd'.

Versatis was indicated for the symptomatic relief of neuropathic pain associated with previous herpes zoster infections (post-herpetic neuralgia, PHN).

The complainant stated that: 'The enclosed poster is being used currently by our field-based teams at Grünenthal to promote the off-label use of versatis [sic]. Not only that, but the poster was written by employees of Grünenthal, a fact which is not acknowledged on the poster, and the cost comparison analysis is flawed and misleading'.

In its detailed response, given below, Grünenthal explained that the item provided by the complainant had the same copy as a poster submitted to the poster session of a meeting of the British Pain Society (BPS) and the accompanying handout.

The Panel noted that the material in this case was the same as that considered in Case AUTH/2330/7/10. The Panel noted that Grünenthal had paid for the printing of the poster and had helped with its submission to the BPS; the company stated that it had not had editorial control of the poster. A consultant pharmacist appeared to have led on the development of the poster. The Panel did not know if the consultant pharmacist had been paid by Grünenthal or had been otherwise retained by the company. A Grünenthal employee had provided information for the poster and was named as the second author although her position with Grünenthal was not declared. The Panel considered it was unacceptable of Grünenthal not to make it clear in its response that one of its employees was named as an author. The Panel considered that given that one of the named authors was a Grünenthal employee, the company could not dissociate itself from the content of the poster. It was difficult to see how in these circumstances Grünenthal could submit it had no editorial control.

The Panel noted that in Case AUTH/2330/7/10 it had decided that given Grünenthal's role in the production of the poster and its content, it was promotional material and thus covered by the Code. The Panel considered that this decision also applied to this case, Case AUTH/2332/7/10.

The Panel noted Grünenthal's submission that the poster had only been used at the BPS meeting and that it had not been used elsewhere. The Panel also noted that the handout had been prepared for the BPS meeting but had not been used. The handout had not been used either proactively or reactively by any Grünenthal staff.

The complainant alleged that the poster was being used by Grünenthal field-based staff to promote the off-label use of Versatis. This was denied by Grünenthal. There was no evidence that the poster was being used by Grünenthal field-based staff and in that regard the Panel ruled no breach of the Code. Following its consideration of this allegation the Panel noted that the use of the poster had been considered in Case AUTH/2330/7/10 and a breach had been ruled as the Panel considered that a claim promoted the product for an unlicensed indication.

Turning back to the case now before it, the Panel then considered the allegations about the failure to acknowledge that one of the authors was a Grünenthal employee and about the cost comparison in relation to the poster displayed at the BPS.

The cost comparison analysis had not been considered in the previous case. The Panel noted that the cost comparison chart gave the daily, monthly and yearly costs per patient for gabapentin 1800mg/day, pregabalin 600mg/day and Versatis 1 patch/day. It appeared to the Panel that there were errors in the calculations.

The Panel also queried the choice of dose for each medicine in that, *inter alia*, it appeared that the costs were based on the maximum dose of pregabalin but not the maximum dose of Versatis or gabapentin as Neurontin. The poster had no data or mention about how the doses compared clinically. It suggested increasing the dose of gabapentin to 3600mg per day which was outside the licensed dose for at least one form of gabapentin (Winthrop). Further the Neurontin (gabapentin (Pfizer))SPC stated that in the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and PHN, efficacy and safety had not been examined in clinical treatment periods longer than 5 months. If a patient required dosing for longer than 5 months the physician should assess the patient's clinical status and determine the need for additional therapy.

The cost comparison used the symbol * next to Versatis but no explanation was given.**

The Panel examined the algorithm which appeared

in the poster and again noted arithmetic mistakes. It was not clear whether the costs in the algorithm were taken from the cost comparison chart or *vice versa*. The Panel also queried the algorithm in that the data for gabapentin and pregabalin took account of patients changed to other therapies whereas all the Versatis patients continued with that medication. The algorithm did not mention the doses of the various medicines.

The Panel considered that the cost comparison was inaccurate and misleading. A breach of the Code was ruled. High standards had not been maintained in relation to the content of the poster and a breach was ruled.

The Panel noted that the employment status of the second author had not been clearly stated. In the Panel's view readers should have been able to view the poster knowing that the second author was a Grünenthal employee. The Panel considered that high standards had not been maintained in this regard and ruled a breach.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel noted its decision that the poster was promotional material for which Grünenthal was responsible. The Panel noted its critical comments on the content of the poster and its ruling of a breach. The Panel was concerned that Grünenthal had certified the poster as promotional material knowing that it was to be displayed at the scientific poster session of the BPS Congress. The employment status of the second author had not been disclosed. Overall, the Panel considered that the company's activities reduced confidence in the pharmaceutical industry and thus ruled a breach of Clause 2.

An anonymous and non-contactable complainant complained about a poster entitled 'Localised Neuropathic Pain' which referred to the use of Versatis (lidocaine plaster), a product supplied by Grünenthal Ltd. At the base of the poster in small type was 'Sponsored by an unrestricted educational grant by Grünenthal UK Ltd'.

Versatis was indicated for the symptomatic relief of neuropathic pain associated with previous herpes zoster infections (post-herpetic neuralgia, PHN).

COMPLAINT

The complainant stated that: 'The enclosed poster is being used currently by our field-based teams at Grünenthal to promote the off-label use of versatis [sic]. Not only that, but the poster was written by employees of Grünenthal, a fact which is not acknowledged on the poster, and the cost comparison analysis is flawed and misleading'.

When writing to Grünenthal, the Authority asked it to respond in relation to Clauses 2, 3.2, 7.2 and 9.1 of the Code.

RESPONSE

Grünenthal explained that the item was not a poster but was intended for use as a handout at the British Pain Society (BPS) poster exhibition. It was not being used by any Grünenthal staff and had never been used. The item was not written by Grünenthal and it acknowledged the support given, not editorial involvement.

In relation to the cost comparison, the poster itself (of which the item in question was intended as a handout) was written by the authors. The main author supplied further justification for the Panel.

Original references were provided. There were two listings and some citations were duplicated. Some were the authors' own calculations. Only some of the references were used in the poster. This was again evidence that Grünenthal did not have editorial control.

Grünenthal explained that a consultant pharmacist and his colleague had an informal discussion with the Grünenthal market access director about the pharmacist's local health economic data and getting it 'published'. As part of the legitimate exchange of medical and scientific information during the development of a medicine, Grünenthal agreed to support this financially and without editorial control. This led to the pharmacist collating his data and asking a health economy liaison manager working for Grünenthal a couple of questions about Versatis. Grünenthal helped with the printing of the poster and submission to the BPS. The poster was peer reviewed by the BPS Scientific Programme Committee and accepted.

A declaration appeared on the bottom of the full sized poster (which was several times bigger than the item at issue) that the poster was 'Sponsored by an unrestricted educational grant by Grünenthal Ltd'. A similar declaration appeared at the bottom of the item in question, being an identical but smaller representation of the poster.

The poster was displayed in the poster session of the BPS independent congress meeting (13-15 April in Manchester). The intention was that the item at issue (the handout) would be available under the poster for delegates to take a copy. However, due to the poor print quality, the handout was removed before the congress opened and never used.

The item had never been sent out by medical information and nor had it been used proactively or reactively by any Grünenthal staff. It was never approved for promotional use. It was certified as a poster handout.

Limited data was provided by Grünenthal but no-one in Grünenthal had editorial control.

With respect to Clause 2, this item was developed to support a poster at an independent national congress. It was never used and so there could be

no discredit upon the pharmaceutical industry.

In relation to Clause 3.2, this item was produced a part of the legitimate exchange of medical and scientific information during the development of a medicine and complied with this clause. The item was never intended or used for promotion. Again, it had never been used.

With regard to Clause 7.2 Grünenthal provided details of the production of the algorithm. It also noted that this was also a peer reviewed abstract reviewed by the BPS Scientific Programme Committee. Clause 7.2 had not been breached.

Finally concerning Clause 9.1, Grünenthal submitted that high standards had been maintained by the intention of limiting the use of this item to the congress' medical and scientific poster session. In the end, it was never used, and certainly not for promotion.

Grünenthal was concerned that this malicious complaint had apparently been made by one of its employees (since this item was never made available outside of Grünenthal) and that this was yet another anonymous, non-contactable complaint about the company. At least in this instance Grünenthal had evidence it could identify and refute any breaches of the Code.

In response to a request for more information, Grünenthal confirmed that the further information requested by the Panel in Case AUTH/2330/7/10 could be used in this case ie Grünenthal stated that the handout was A3 in size. It was common practice to provide a reprint of a poster presentation at a scientific conference. Organisers often requested reprints from poster presenters. Grünenthal thus printed a number of handouts which, apart from size, were identical to the poster.

In response to a further request for more information Grünenthal confirmed that the poster had only been used at the BPS meeting in April and no further use had been made of it. No-one at Grünenthal had been provided with copies of the poster.

PANEL RULING

The Panel noted that the material in this case was the same as that considered in Case AUTH/2330/7/10. The Panel noted that Grünenthal had paid for the printing of the poster and had helped with its submission to the BPS; the company stated that it had not had editorial control of the poster. A consultant pharmacist appeared to have led on the development of the poster. The Panel did not know if the consultant pharmacist had been paid by Grünenthal or had been otherwise retained by the company. A Grünenthal employee had provided information for the poster and was named as the second author although her position with Grünenthal was not declared. The Panel considered it was unacceptable of Grünenthal not to make it clear in its response that one of its employees was named as an author. The Panel considered that given that one of the named authors was a Grünenthal employee, the company could not dissociate itself from the content of the poster. It was difficult to see how in these circumstances Grünenthal could submit it had no editorial control.

The Panel noted that in Case AUTH/2330/7/10 it had decided that given Grünenthal's role in the production of the poster and its content it was promotional material and thus covered by the Code. The Panel decided that this decision also applied to the present case, Case AUTH/2332/7/10.

The Panel noted Grünenthal's submission that the poster had only been used at the BPS meeting in April and that it had not been used elsewhere. The Panel also noted that the handout had been prepared for the BPS meeting but had not been used. The handout had not been used either proactively or reactively by any Grünenthal staff.

The complainant alleged that the poster was being used by Grünenthal field-based staff to promote the off-label use of Versatis. This was denied by Grünenthal. There was no evidence that the poster was being used by Grünenthal field-based staff and in that regard the Panel ruled no breach of Clauses 2, 3.2, 7.2 and 9.1. Following its consideration of this allegation the Panel noted that the use of the poster had been considered in Case AUTH/2330/7/10 and a breach of Clause 3.2 had been ruled as the Panel considered that a claim promoted the product for an unlicensed indication.

Turning back to the case now before it, the Panel then considered the allegations about the failure to acknowledge that one of the authors was a Grünenthal employee and about the cost comparison in relation to the poster displayed at the BPS.

The cost comparison analysis had not been considered in the previous case. The Panel noted that the cost comparison chart gave the daily, monthly and yearly costs per patient for gabapentin 1800mg/day, pregabalin 600mg/day and Versatis 1 patch/day.

It appeared to the Panel that there were errors in the calculations as the daily cost of gabapentin (£1.23) would give a monthly cost of £34.44 and not £34.49 as given in the chart. This daily cost would give an annual cost of £447.72 and not £448.38 as given in the chart. Similar errors were made for Versatis in that based on the daily cost of £2.41 the monthly cost should be £67.48 and yearly cost £877.24 not £67.57 and £878.45 respectively as given in the chart.

The Panel queried the choice of dose. It appeared from the Versatis summary of product characteristics (SPC) that the maximum recommended dose was three plasters applied simultaneously for 12 hours (Section 5.2). The subsequent plaster free interval must be at least 12

hours (Section 4.2 of the SPC). Pregabalin for neuropathic pain could be given at a maximum dose of 600mg/day (Lyrica SPC). Gabapentin for neuropathic pain could be given at a daily maximum of 3600mg (Neurontin SPC (Pfizer)) but only the cost of the 1800mg/day dose was detailed in the poster. The Neurontin SPC stated that in the treatment of peripheral neuropathic pain such as painful diabetic neuropathy and PHN, efficacy and safety had not been examined in clinical treatment periods longer than 5 months. If a patient required dosing for longer than 5 months the physician should assess the patient's clinical status and determine the need for additional therapy.

It appeared that the costs were based on the maximum dose of pregabalin but not the maximum dose of Versatis or gabapentin as Neurontin. The poster had no data or mention about how the doses compared clinically. It suggested increasing the dose of gabapentin to 3600mg per day which was outside the licensed dose for at least one form of gabapentin (Winthrop).

The cost comparison used the symbol *** next to Versatis but no explanation was given.

The Panel examined the algorithm which appeared in the poster. It noted that 3300 patients with persistent localised neuropathic pain needed long term prescribing of medicines. The algorithm allocated 70% of patients to gabapentin (2145 patients) whereas 70% of 3300 was 2310. (This figure had been corrected on the material submitted by Grünenthal to substantiate the poster). Of the patients on gabapentin 80% would continue long term giving an overall figure of 1716 on the poster whereas 80% of 2310 was 1848. (This figure had been corrected on the material submitted by Grünenthal to substantiate the poster). Thus the algorithm was incorrect. It was not clear whether the costs in the algorithm were taken from the cost comparison chart or *vice versa*. The Panel also queried the algorithm in that the data for gabapentin and pregabalin took account of patients changed to other therapies whereas all the Versatis patients continued with that medicine. The algorithm did not mention the doses of the various medicines.

The Panel considered that the cost comparison was not accurate and was misleading. A breach of Clause 7.2 was ruled. High standards had not been maintained in relation to the content of the poster and a breach of Clause 9.1 was ruled.

The Panel noted that the employment status of the second author had not been clearly stated. In the Panel's view readers should have been able to view the poster knowing that the second author was a Grünenthal employee. The Panel considered that high standards had not been maintained in this regard and ruled a breach of Clause 9.1.

The Panel noted that Clause 2 was a sign of particular censure and reserved for such use. The Panel noted its decision that the poster was promotional material for which Grünenthal was responsible. The Panel noted its critical comments on the content of the poster and its ruling of a breach of Clause 7.2. The Panel was concerned that Grünenthal had certified the poster as promotional material knowing that it was to be displayed at the scientific poster session of the BPS Congress. The employment status of the second author had not been disclosed. It considered that taking all the circumstances into account in this instance the company's activities reduced confidence in the pharmaceutical industry and thus ruled a breach of Clause 2.

Complaint received **12 July 2010**

Case completed **19 August 2010**